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1 UNITED STATES OF AMERICA

2 NUCLEAR REGULATORY COMMISSION

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4 ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

5 (ACMUI)

6 + + + + +

7 MONDAY,

8 JULY 8, 2002

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10 ROCKVILLE, MARYLAND

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12 The ACMUI met at the Nuclear Regulatory
13 Commission, Two White Flint North, Auditorium, 11545
14 Rockville Pike, at 1:00 p.m., Manuel Cerqueira, M.D.,
15 Chairman, presiding.

16 COMMITTEE MEMBERS:

17 MANUEL CERQUEIRA, M.D., Chairman
18 JEFFREY A. BRINKER, M.D., Member
19 DAVID A. DIAMOND, M.D., Member
20 DOUGLAS F. EGGLI, M.D., Member
21 NEKITA HOBSON, Member
22 RALPH P. LIETO, Member
23 LEON S. MALMUD, M.D., Member
24 RUTH McBURNEY, Member
25 SUBIR NAG, M.D., Member

1 COMMITTEE MEMBERS: (cont.)
2 SALLY WAGNER SCHWARTZ, Member
3 RICHARD J. VETTER, Ph.D., Member
4 JEFFREY F. WILLIAMSON, Ph.D., Member
5
6 ACMUI STAFF PRESENT:
7 ANGELA WILLIAMSON
8 LLOYD BOLLING
9 JOHN HICKEY, Designated Federal Official
10
11 ALSO PRESENT:
12 WILLIAM R. UFFELMAN, ESQUIRE
13 LYNNE A. FAIROBENT
14
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1 C-O-N-T-E-N-T-S

2 Call to Order and Opening Remarks
3 Dr. Manuel Cerqueira, Chairman 5
4 Opening Remarks 6
5 John Hickey
6 Teleconference Discussion of June 21, 2002 . . . 8
7 Subcommittee Recommendations for the Training
8 and Experience Requirements in the Revised
9 10 CFR Part 35, Medical Use of Byproduct Material
10 Introduction and Rationale 5
11 Section 35.50, Training for Radiation 7
12 Safety Officer
13 Section 35.390, Training for Use of 34
14 Unsealed Byproduct Material for Which
15 a Written Record is Required
16 Section 35.392 and 3.394, How to Deal 42
17 with the Use of Sodium I-131
18 Section 35.490, Training for the Use 44
19 of Manual Brachytherapy Sources
20 Section 35.491, Ophthalmic Use of 52
21 Strontium-90
22 Section 35.690, Training for Use of 52
23 Remote After-Loader Units, Teletherapy
24 Units, and Gamma Stereotactic
25 Radiosurgery Units

C-O-N-T-E-N-T-S

Section 35.51, Training for Authorized 57
Medical Physicists
Section 35.55, Training for an 62
Authorized Nuclear Pharmacist
Section 35.190, Training for Uptake 78
Dilution and Exclusion Studies
Section 35.290, Energy and Localization 82
Studies
Section 35.590, Use of Sealed Sources for . . . 88
Diagnosis
Agreement State Implementation of the 94
10 CFR Part 35 Training and
Experience Requirements
Status of the New ACMUI Appointments and 98
Future Vacancies
Comments from the Audience 100
General Discussion 110

1 P-R-O-C-E-E-D-I-N-G-S

2 1:04 p.m.

3 CHAIRMAN CERQUEIRA: On behalf of the
4 ACMUI Committee, I would like to bring this telephone
5 conference to order.

6 The main purpose of today's meeting is to
7 go over the recommendations of the NRC ACMUI
8 Subcommittee on Training and Experience Requirements
9 that were submitted to the main Committee and to the
10 NRC, and are now going to be discussed by the main
11 Committee, and, hopefully, we will be able to reach
12 some conclusions on these revised training and
13 experience requirements, so we will fix some of the
14 problems with the Part 35 revision.

15 Before we get into that, on behalf of the
16 Committee, I would like to thank John Hickey for all
17 the work that he has done with the Committee over the
18 last year and a half, John. He's going to be moving
19 on to other areas within the NRC, and we appreciate
20 all the work that he has put into it. I personally
21 would like to thank him for helping us through this
22 fairly elaborate process. Thank you, John.

23 MR. HICKEY: Thank you, Dr. Cerqueira.

24 CHAIRMAN CERQUEIRA: Does everyone here
25 have the version that is dated June 27th, 2002? Now

1 there's an introduction and a rationale which goes
2 into some of the background material as to why this
3 was necessary. Does anybody have any comments or
4 changes they would like to make to the introduction or
5 the rationale?
6 MR. HICKEY: Dr. Cerqueira, this is John
7 Hickey. If I could just go over the arrangements with
8 the members?
9 I believe some more people just came on
10 the bridge. Is Dr. Nag on?
11 DR. EGGLI: No, this is Dr. Douglas Eggli.
12 MR. HICKEY: Okay, thank you, Dr. Eggli.
13 Is Dr. Nag on? Is Ms. Hobson on?
14 MS. HOBSON: Yes.
15 MR. HICKEY: Okay. This is John Hickey
16 from NRC headquarters. We would like to welcome Dr.
17 Eggli, participating in his first meeting. He was
18 recently appointed as a nuclear medicine physician.
19 He's from Pennsylvania State University, Hershey
20 Medical Center.
21 Also, we will welcome Dr. Brinker, as a
22 new appointee interventional cardiologist. He has
23 participated in previous meetings as a guest, and he
24 has already met the other members of the Committee.
25 This is an open meeting. There are

1 members of the public present here in NRC
2 headquarters, and the meeting is being transcribed.
3 Dr. Cerqueira, I will turn it back to you.
4 CHAIRMAN CERQUEIRA: Okay, thank you very
5 much, John, for those comments.
6 We have four hours for this telephone
7 conference. Hopefully, we will be done much sooner
8 than that.
9 Does the Committee feel comfortable just
10 going through the various sections and giving comments
11 and criticisms? I think that would be the most
12 logical way to approach it.
13 Again, going back to the Introduction and
14 Rationale, any unhappiness with that or changes that
15 people feel would be appropriate?
16 (No response.)
17 Okay, the no comments is an acknowledgment
18 of acceptance of what's been stated.
19 MR. HICKEY: This is John Hickey. Those
20 on the phone, when you do speak, please identify
21 yourselves for the transcriber.
22 CHAIRMAN CERQUEIRA: All right, so the
23 next section will be 35.50, Training for Radiation
24 Safety Officer. I think the changes here reflect the
25 Subcommittee meeting that was held in June.

1 DR. WILLIAMSON: This is Jeff Williamson.
2 May I make a suggestion then?
3 CHAIRMAN CERQUEIRA: Yes.
4 DR. WILLIAMSON: I think it might be
5 helpful if the Subcommittee member who is responsible
6 for each section perhaps briefly outlined what the
7 changes were.
8 CHAIRMAN CERQUEIRA: That would be
9 worthwhile. Who is responsible for the Radiation
10 Safety Officer's section? Was that --
11 DR. VETTER: Richard Vetter was
12 responsible for that, speaking.
13 Just to clarify, if I may, Jeff, when you
14 said, "outline the changes," do you mean from the June
15 21st document?
16 DR. WILLIAMSON: No, I think that this is
17 a broader group. So I think it would be useful if you
18 just basically went over the new training and
19 experience requirement and highlighted the changes
20 relative to the recently-published Part 35.57.
21 DR. VETTER: Right, okay. The recently-
22 published 35.50 -- actually, 35.57 is the grandfather
23 clause, but the recently-published 35.50, that is the
24 revised Part 35, did not list boards. The
25 Subcommittee, as we discussed whether or not to list

1 boards, decided that -- we didn't actually take a
2 vote, but I think the consensus was that we would like
3 to recommend that some boards actually be hard-wired
4 in, if you will, to the regulation. That is, those
5 that meet the specific criteria that are identified be
6 hard-wired in, and that is paragraph (a).
7 So relative to the issue of radiation
8 safety, there are three boards that meet those
9 requirements, and they are listed here. Those three
10 boards meet the requirements of paragraph (b).
11 Now the recently-published Part 35, as you
12 recall, required that any board that would be
13 recognized by NRC satisfy the requirements, the very
14 specific training requirements, which are now
15 paragraph (c), and, in addition -- I'm sorry, the
16 boards must require that applicants meet those
17 requirements and also require that the applicant
18 provide a preceptor letter that is signed by someone
19 who testifies, if you will, that the individual is
20 competent.
21 In the charge to the Committee, we were
22 asked to develop a recommendation where being board-
23 certified would be the default. So this first section
24 is written in that way, that anyone who would fulfill
25 the responsibilities of Radiation Safety Officer must

1 be certified by one of the listed boards or by another
2 board that meets the requirements of paragraph (b).
3 That is, in this particular case you hold
4 a degree; you have a certain number of years of
5 experience, and you have a supervising physicist or
6 RSO testify, if you will, that you, in fact, have
7 completed that training requirement. That is, the
8 board would have to have a letter from the supervising
9 physicist or RSO testifying that you have completed,
10 that the RSO has completed -- that the applicant has
11 completed the training.
12 Then, finally, the Committee felt very
13 strongly that if individuals could pass the
14 examination of a board of peers that tested in the
15 subject area -- and in this case it is primarily
16 radiation safety, but also it is some physics
17 implementation, and so forth -- that that, in fact,
18 demonstrates that the individual has the knowledge to
19 do the job.
20 So paragraph (b) is actually a list of the
21 criteria that any new board would have to meet in
22 order to be recognized by the NRC, and the three
23 boards listed in paragraph (a) do, indeed, meet those
24 criteria.
25 Paragraph (c), then, is unchanged. That's

1 basically the alternate pathway. We did not make any
2 changes in that, with the exception of the very last
3 item in paragraph (c) which has to do with written
4 certification. There again, we removed the -- let's
5 see, was there -- I need clarification. Was there a
6 requirement? Yes, there was, in that paragraph there
7 was a requirement that the preceptor sign that the
8 individual is competent to practicum. So this
9 paragraph (c)(3) does not have that in it.
10 Then paragraph (d) is the basically
11 unchanged certainly philosophy. That is, anyone who
12 can be approved to be an authorized user, medical
13 physicist, or nuclear pharmacist can also serve as the
14 Radiation Safety Officer.
15 Then a second charge of the Subcommittee
16 was to decouple the modality-specific training from
17 the board. Paragraph (e) does that. So this is new.
18 So, in other words, paragraph (e) says, it
19 doesn't matter whether you're board-certified or go
20 through the alternate pathway; you must demonstrate
21 that the licensee must assure that the individual who
22 will serve as Radiation Safety Officer has the
23 training in radiation safety, regulatory issues,
24 emergency procedures, proposed clinical procedures,
25 and so forth, for any modality for which the licensee

1 is licensed or seeks authorization.

2 So that, in a sense, decouples it from the

3 board, but the board doesn't have to assure that the

4 individual has the experience in the specific

5 modality, but the licensee must assure that the

6 Radiation Safety Officer has that experience.

7 MS. HOBSON: I'm not sure there's anything

8 about that on my copy.

9 MR. HICKEY: Excuse me, Ms. Hobson, could

10 you speak up or try to increase the volume in some

11 way?

12 MS. HOBSON: Well, I was just saying that

13 my copy as my computer downloaded it does not include

14 the (a), (b), (c), (d), and (e) that Dr. Vetter was

15 referring to. Am I the only one that has that kind of

16 a copy? Is it a peculiarity of my computer?

17 MS. McBURNEY: Are you on 35.50?

18 MS. HOBSON: Yes.

19 MS. McBURNEY: Training for Radiation

20 Safety Officer?

21 MS. HOBSON: Yes.

22 MS. McBURNEY: It should have.

23 MS. HOBSON: No, no.

24 DR. VETTER: It must be your system. If

25 you have a specific question on a specific paragraph,

1 just mention that.

2 MS. HOBSON: Okay, I did have a question

3 about if any additional boards besides the three that

4 are listed here would go through a process of becoming

5 accepted by the NRC before their certification would

6 be accepted?

7 DR. VETTER: That is our recommendation,

8 yes.

9 MS. HOBSON: Okay, all right. Thank you.

10 CHAIRMAN CERQUEIRA: Again, this is Manuel

11 Cerqueira. If people could identify themselves, it

12 will make it easier for the transcriptionist.

13 I would like to add one point that is the

14 result of a Subcommittee meeting. We had quite a

15 discussion about competence, and everyone agreed that

16 completing the training and experience is what, with

17 the certification from the supervising individual,

18 would be required. This is somewhat different than we

19 had included in the original, but I think, as a result

20 of listening to the boards and as a result of the

21 discussions, most of us felt comfortable with

22 "completed the training and experience," and this

23 would be used throughout the document, not just for

24 the Radiation Safety Officer, but for the other

25 individuals as well.

1 Okay, any other discussion on the
2 Radiation Safety Officer?
3 MR. LIETO: Are we opening it up to
4 specific comments? This is Ralph Lieto speaking.
5 CHAIRMAN CERQUEIRA: Yes.
6 MR. LIETO: I have a comment, and I am
7 just going to repeat some of the things that I had
8 sent previously to the NRC. This was a comment
9 throughout all the training.
10 For example, if we go to 35.50, Part (b),
11 No. 3, which says, "to provide a written certification
12 from the supervising physicist or RSO," individuals
13 don't certify, and I think Dick recognized this.
14 My suggestion was that using the word
15 "attestation," or if there is another term that the
16 NRC would prefer that for now I guess to the preceptor
17 concept, I think we maybe want to change that all the
18 way throughout, because I don't think anybody is going
19 to want to sign a statement that they certify an
20 individual. I don't even know if they can, but that
21 is a comment for this specific part and also
22 throughout the training requirements for the
23 authorized users.
24 DR. VETTER: Richard Vetter.
25 I think that is a very good point,

1 particularly since it falls within the paragraph that
2 is talking about certification boards, using the word
3 "certification" in two different contexts there. So
4 I would support Ralph's suggestion that we change it
5 from "certification" to some other word, "attestation"
6 or "written documentation." I don't know what is the
7 best word, but I do agree with what he said.
8 MR. LIETO: My next comment has to do with
9 the paragraph above it on No. 2 and maybe also to Dick
10 and to the NRC staff. I guess there is some wording
11 in there that I thought I'm a little confused by, the
12 word "responsible professional experience." I guess
13 I am kind of bothered by that word "responsible" being
14 in there and would maybe recommend that we just delete
15 that word.
16 DR. VETTER: Where's the word
17 "responsible"?
18 MR. LIETO: It's No. 2. It would be
19 (b)(2) where it says, "to have five or more years of
20 responsible professional experience." I don't know if
21 that is maybe taking verbatim from some other
22 reference.
23 DR. VETTER: That is verbatim from one of
24 the boards.
25 MR. LIETO: Okay.

1 DR. VETTER: But we don't need to go
2 verbatim from the board. I don't have a problem with
3 deleting that.
4 MR. LIETO: The other thing was, in that
5 same paragraph, was professional experience versus
6 applied health physics. I should say professional
7 experience in health physics versus applied health
8 physics. Is there some place where that is clarified?
9 I know it is not in here, but, I mean, is there a
10 reference that can be cited where there is that
11 distinguishment between those two terms of
12 radiologies.
13 DR. VETTER: This is Richard Vetter.
14 I think the reason the word "applied" is
15 there is so that we assure that the person applying to
16 become certified is not someone who is simply a book-
17 learner; that is, they have never been in an actual
18 operating environment.
19 We are suggesting that the individual
20 actually has to have worked in the environment. In
21 other words, it would be difficult for a person who
22 went right from graduate school into a faculty
23 position, never actually practiced, to meet this
24 requirement.
25 Just let me expand on that a little bit

1 more. It is not that we are trying to exclude anyone.
2 MR. LIETO: Right.
3 DR. VETTER: It is just that we felt that
4 it was important that the individual actually has been
5 in an actual environment practicing health physics,
6 taking measurements, doing calculations, doing all
7 those sorts of things, doing surveys, so that they
8 actually have some real experience. That was the
9 purpose of that.
10 MS. SCHWARTZ: Maybe you could change --
11 Sally Schwartz -- change the wording to "three years
12 working in health physics"?
13 DR. VETTER: This is Richard Vetter.
14 You're also working if you are sitting at
15 a desk doing calculations, and you've never actually
16 took on a survey meter.
17 CHAIRMAN CERQUEIRA: This is Manuel
18 Cerqueira.
19 Ralph, I mean you see the intent, what we
20 are trying to get at. Do you agree with requiring
21 some practical applied requirement as opposed to
22 classroom?
23 MS. McBURNEY: This is Ruth McBurney.
24 I think that goes also to the start of
25 that No. 2, where you can have graduate training

1 substituting for two years, but you've got to have at
2 least three of those years in applied health physics.
3 You couldn't just have graduate training or, as Rich
4 mentioned, faculty-type work.
5 MR. LIETO: But the applied would not, if
6 I am understanding correctly, would not necessarily
7 have to be in a medical or modality-specific
8 environment, is that correct?
9 DR. VETTER: This is Richard Vetter. That
10 is correct.
11 MR. LIETO: Okay.
12 DR. VETTER: Paragraph (e) takes care of
13 that.
14 MR. LIETO: Okay, right. Okay. All
15 right.
16 CHAIRMAN CERQUEIRA: So can we keep that
17 as is, Ralph?
18 MR. LIETO: I'm sorry?
19 CHAIRMAN CERQUEIRA: We can keep that as
20 through using "applied health physics"?
21 MR. LIETO: That's fine.
22 CHAIRMAN CERQUEIRA: We'll take
23 "responsible" out.
24 Okay, other comments?
25 MR. LIETO: This is Ralph Lieto again.

1 On the last paragraph, that Section (e),
2 where it decouples from the board certification, just
3 to be sure that I understand this correctly, because
4 there has been a question brought up. This would
5 allow, then, say, a teletherapy physicist to be an RSO
6 over, say, a nuclear medicine area if they can
7 demonstrate the training that meets the requirements
8 of Section (e)? Is that correct, Dr. Vetter?
9 DR. VETTER: Yes, that is correct.
10 MR. LIETO: Okay.
11 DR. WILLIAMSON: This is Jeff Williamson.
12 I would like to ask Mr. Hickey if he agrees with that
13 interpretation.
14 MR. HICKEY: This is John Hickey.
15 The intent was -- I believe this is not
16 the Subcommittee's wording. I think this is from the
17 existing regulation. The intent was if they have
18 experience with similar types of materials. So if you
19 include a paragraph (e) which says they have to have
20 -- this, taken in total, would say that they have to
21 have the right training experience and experience with
22 the radioactive material. So I would agree with Dr.
23 Vetter.
24 DR. WILLIAMSON: Because why I asked, it
25 says in (d), "has experience with the radiation safety

1 aspects of similar types of use of byproduct material
2 for which the individual has Radiation Safety Officer
3 responsibilities."
4 I guess, then, what it also means is, by
5 extension, a nuclear medicine physician could become
6 the RSO of a broad scope licensee?
7 DR. VETTER: This is Richard Vetter.
8 The answer, my opinion, the answer to that
9 is yes, if he or she meets the requirements of (d) and
10 (e), or specifically (d).
11 DR. WILLIAMSON: Yes, you know, it is not
12 clear to me, I guess what I am saying, it is not clear
13 to me that the requirements in (d) are the same as the
14 requirements in (e). I mean, one interpretation of
15 (d) and (e) is that (e) provides for the less
16 stringent training and experience that's modality-
17 specific, and the intent of (d) is kind of to limit
18 the person to be an RSO of an operation that is more
19 or less limited to what the person is already
20 authorized to do as an authorized user or AMP.
21 DR. VETTER: Yes, I agree with that. This
22 is Richard Vetter. I agree with him.
23 DR. WILLIAMSON: And, you know, its
24 intention is to serve the small single or small
25 licensees that have maybe one or two modalities

1 available, such as only nuclear medicine or only
2 teletherapy or only brachytherapy, in which the most
3 qualified person available to do that is probably an
4 authorized user or AMP working with the specific
5 modality.
6 MS. McBURNEY: This is Ruth McBurney, and
7 it is probably a medical physicist in a therapy that
8 was a trained therapy physicist would probably meet
9 the alternative pathway of (c) by virtue of their
10 education and most of the experience, and if they had
11 just a little extra in nuclear medicine, probably they
12 could be authorized as an RSO for nuclear medicine.
13 MR. LIETO: This is Ralph Lieto.
14 The comment that Jeff brought up, that
15 seems to present sort of I guess a danger, for lack of
16 a better word, that would allow someone with minimal
17 qualifications to be RSO over extremely multiple-
18 modality-type licensees. Well, you know, do we want
19 to do anything about that?
20 DR. WILLIAMSON: It would be some concern,
21 I guess. I can see it cutting both ways, but I want
22 to remind the Committee and Subcommittee of one of the
23 positions that Bill Hindee presented in behalf of the
24 ABR. He basically notes that in Subpart (c), the old
25 requirement, they list in there anybody boarded by the

1 American Board of Radiology, American Board of Medical
2 Physics and Radiation Oncology, and a bunch of other
3 things. They are listed as members of the -- they can
4 be RSOs.
5 So on the negative side, it seems to me we
6 are making it more difficult for certified therapy
7 physicists to be RSOs of broad-scope licensees, and
8 maybe in some cases that might be the best and most --
9 how could I say? -- safety-conscious decision for a
10 given licensee to make, as the alternative being
11 somebody who is not onsite, who's a consultant RSO,
12 and is not there, and so on. That is kind of an
13 awkward dilemma to be put in. So I think it's
14 possible that it cuts on the negative side a bit.
15 In another direction, it can cut on the
16 negative side by, as you pointed out, Ralph, allowing
17 somebody that really doesn't have the basic education
18 and technical knowledge to absorb all of these
19 modalities and their safety aspects, and doesn't have
20 a global enough knowledge of the regulations, and so
21 on, to be the RSO of a really complex program. That
22 is another concern. So it could also let in some
23 underqualified people, and it might also cut out some
24 mainly well-qualified people.
25 MR. HICKEY: Could the last speaker

1 identify himself?

2 DR. WILLIAMSON: I'm sorry, I couldn't

3 understand what you said.

4 MR. HICKEY: Could you identify yourself,

5 please? Didn't catch your name.

6 CHAIRMAN CERQUEIRA: Jeff Williamson.

7 DR. WILLIAMSON: I'm sorry, Jeff

8 Williamson.

9 CHAIRMAN CERQUEIRA: This is Manuel

10 Cerqueira.

11 So how do you want to handle this,

12 Ralph --

13 MR. LIETO: I guess I have been answered

14 satisfactorily on that. I see this as, I guess, a

15 double-edged sword here, but I guess we don't want to

16 make it overly restrictive in the sense that we do cut

17 out viable candidates for this position.

18 One thing that I would just want to add to

19 this, as I had in my previous comment, was that it

20 talks about training requirement being satisfied and

21 by training under a supervised individual. I guess I

22 would just like to add that there be some attestation

23 statement, again, about the satisfactory completion of

24 that training under Item (e).

25 (Pause.)

1 In other words -- this is Ralph Lieto
2 again -- maybe a statement to the effect that, quote,
3 "supervising medical physicists or Radiation Safety
4 Officer must attest in writing to the satisfactory
5 completion of the training."
6 DR. VETTER: This is Richard Vetter.
7 Our intent here was to put the
8 responsibility on the licensee to assure that the
9 Radiation Safety Officer had the training needed. We
10 assume that licensing, if they wanted to pursue it,
11 would ask the licensee to verify that they, in fact,
12 did have the training.
13 So what training are we talking about?
14 The last sentence, "the training requirement may be
15 satisfied by meeting training supervised by an
16 authorized medical physicist," et cetera, "who is
17 authorized for the modality." So a licensee would
18 then have to be able to demonstrate that that training
19 occurred.
20 I am not arguing against what you are
21 saying, Ralph. I am just saying that it is our intent
22 here was for the burden to be put on the licensee, and
23 not to prescribe how, in fact, they could demonstrate
24 that the training had occurred.
25 MR. LIETO: So you're suggesting that --

1 DR. VETTER: I guess I was just making it
2 a little bit more explicit that there needs to be a
3 documented -- in other words, I could see the licensee
4 could get this from the supervising physicist or RSO,
5 yet it might not be in writing. I guess I was just
6 saying that there needs to be a documentation that the
7 training was completed satisfactorily; that's all.
8 CHAIRMAN CERQUEIRA: Well, Ralph, this is
9 Manuel Cerqueira.
10 On (b)(3) you had us take certification
11 out for completed the training and experience, and now
12 here you want to put it back in some way that there is
13 a documented competency or satisfactorily conclusion.
14 Why would it be different in (b)(3) than in --
15 DR. VETTER: Well, in (3) you're asking
16 for -- it uses the word "certification."
17 CHAIRMAN CERQUEIRA: Right.
18 DR. VETTER: I'm just kind of using
19 Webster's definition of attestation and just saying
20 that the licensee needs to have this document that the
21 person has received, completed this training
22 satisfactorily; that's all.
23 DR. WILLIAMSON: This is Jeff Williamson.
24 But isn't it the case that, if this is
25 required, there is an understood obligation of the

1 licensee to be able to provide documentation that this
2 training occurred if an inspector asks for it?
3 DR. VETTER: Right, but who does it come
4 from? Let's say you hired a person and he says, "Yes,
5 I have it. I'll write you a document that says I have
6 it," as opposed to the person that did the actual
7 supervision of the training. That is what I was
8 saying.
9 DR. WILLIAMSON: I am just concerned that
10 we are making more complexity and bookkeeping and
11 making it more prescriptive than it needs to be. I
12 mean, there is kind of a not-so-well-established for
13 RSO, but I think there are fairly well-accepted
14 pathways for getting this modality-specific training
15 for authorized users and authorized medical physicists
16 with the different modalities.
17 I think to put in place another sort of
18 level of formal letters, I just don't see why it is
19 necessary.
20 MR. LIETO: Well, this is Ralph Lieto
21 again.
22 I seem to recollect that there was a
23 concern -- I don't know if it was brought up in the
24 Committee meetings or at the hearings or where -- that
25 there was a problem and there were requirements for

1 these trainings, and so forth, but no one had to
2 necessarily attest to the fact that the person
3 completed it satisfactorily. In other words, they
4 could say, "Yes, this person did the training, but
5 they're really not competent to function
6 independently."
7 I think that was a concern that was raised
8 several times in the past. My recommendation was
9 simply to address that issue: that if you're going to
10 say that this person is competent to be an RSO, then
11 you should be willing -- and you supervised that
12 training -- then someone should be willing to put
13 their name that they were competent.
14 DR. WILLIAMSON: This is Jeff Williamson
15 again.
16 We actually did discuss the general issue
17 a lot. This is far more general than this paragraph
18 (e), because the general position that the
19 Subcommittee took was that the preceptor statement
20 definition as written in the recently-published Part
21 35 was so strong it required the preceptor to attest
22 to the clinical competence of the applicant and the
23 ability to practice independently; that we felt that
24 there would be a problem because preceptors would be
25 unwilling to sign such vague and unquantifiable

1 statements, for fear of taking on -- for fear of
2 future liability, if it turned out there were some
3 incident down the line involving the applicant.
4 So we backed off and wanted to go with
5 nothing more strong than satisfactorily completed the
6 training program, which, you know, is black and white
7 and can be quantified that they did or did not, and
8 leave it at that.
9 CHAIRMAN CERQUEIRA: This is Manuel
10 Cerqueira.
11 I would like to hear some other Committee
12 members kind of give us their view on this. Ruth,
13 what do you think would be -- I mean, we had this
14 discussion through multiple years of developing Part
15 35 revisions and then also during the Subcommittee.
16 I thought that this language had sort of finally
17 captured what we felt was putting enough teeth into
18 it, but not making it so restrictive. Ruth?
19 MS. McBURNEY: Yes, this is Ruth.
20 I think that, from a regulatory
21 standpoint, if somebody wants, if an inspector wanted
22 to see that somebody had completed that training, that
23 there might be some sort of document available. But
24 I think we decided not to put it into rule as far as
25 requiring that to be submitted as a licensing, as a

1 part of the licensing process.

2 CHAIRMAN CERQUEIRA: Well, I think that

3 was the general --

4 MS. McBURNEY: For the modality-specific

5 training.

6 CHAIRMAN CERQUEIRA: Dr. Eggli, this is a

7 whole new issue for you in some ways. Do you have any

8 comments on this particular requirement?

9 DR. EGGLI: Well, I participated in one of

10 the early Part 35 workshops. The issue is, wherever

11 you set the bar for training and experience, no one

12 should be able to crawl under the bar rather than leap

13 over it. Having no defined documentation pathway

14 leaves the potential for people to crawl under the

15 bar.

16 CHAIRMAN CERQUEIRA: Okay, although,

17 again, the SNM gave us pretty strong language that

18 none of this should be required. So that runs a

19 little bit against what some of the earlier

20 recommendations have been.

21 Dr. Malmud, your comments? Dr. Malmud?

22 DR. MALMUD: Yes, my feeling is that, when

23 we are overly prescriptive, we create new problems

24 that would not otherwise have occurred.

25 Are you able to hear me?

1 CHAIRMAN CERQUEIRA: Yes, yes.
2 DR. MALMUD: My own feeling is that it
3 would be better to certify that the individual had
4 completed a training program. What the individual has
5 done subsequent to the training program is not, in my
6 mind, something that can be attributed to the training
7 program itself, which addresses the issue that was
8 raised about a liability of the person who certifies
9 for the training program being held responsible
10 forever.
11 I think we are responsible for that which
12 we did while we were in charge of the training
13 program. If the individual loses his capability for
14 one reason or another beyond that, I don't think we
15 can be held responsible for that.
16 So I would lean toward the less
17 prescriptive, and running the risk, I agree, of
18 someone crawling under the line rather than jumping
19 over it. But I don't know that there is any way in
20 human behavior that we can prevent every possible
21 breach from occurring.
22 My preference would be to be less
23 prescriptive.
24 CHAIRMAN CERQUEIRA: Okay, let's have
25 David's comments then. Thank you.

1 DR. WILLIAMSON: This is Jeff Williamson.
2 Another point to be made is that this is
3 a new requirement. It is not present in the Subpart
4 (j). It does not seem that there is any evidence that
5 this has caused a crisis in public safety. Like are
6 these whole lines of people crawling under the wire
7 endangering the radiation safety of numerous
8 operations? The existing system works. So why make
9 it more difficult?
10 DR. MALMUD: Yes, the most significant
11 issue that we had at our institution was with a very
12 well-trained person who, for some reason or another,
13 wasn't behaving well. So I don't know that the issue
14 of being overly prescriptive would not have dealt with
15 that issue, while at the same time I agree we can't
16 leave the door wide open.
17 So my tendency would be to go with those
18 members of the Committee who prefer being less
19 prescriptive.
20 CHAIRMAN CERQUEIRA: Okay, David Diamond,
21 do you have any feelings on this issue?
22 DR. DIAMOND: I actually rather like the
23 language as it is right now. I think that it is not
24 too overly prescriptive. I think it gives enough
25 guidance, and I like the way it is right now.

1 CHAIRMAN CERQUEIRA: Okay, good. Dr. Nag?
2 (No response.)
3 I guess he's not on at this point.
4 Sally, do you have any comments?
5 MS. SCHWARTZ: No, I think that as it is
6 written is an acceptable --
7 CHAIRMAN CERQUEIRA: Okay. So I think we
8 have had a fairly good discussion on this. I think
9 people understand your concerns, but I think the
10 feeling is that, as it is currently written, it would
11 still deal with some of the issues that you have
12 brought up.
13 DR. MALMUD: And that's my interpretation
14 as well. This is Malmud again.
15 CHAIRMAN CERQUEIRA: Yes. Okay, well,
16 again, just on behalf of my constituency, the nuclear
17 cardiologists, again, I would love to get a
18 clarification also, but if someone is an authorized
19 user so that a private practice cardiology office, an
20 authorized user under (2)(D) of this section would be
21 able to qualify as a Radiation Safety Officer. That
22 was brought up during the discussion, but I just
23 wanted to make sure that that was agreed upon by
24 everyone.
25 Okay, well, I think we have had a fairly

1 good discussion on this. Some of these issues will
2 come up with some of the other ones, and we will
3 probably won't have to go into it in as much detail.
4 So other than a few changes under (b)(2),
5 taking out "responsible" and then trying to come up
6 with a different word under (b)(3) for certification,
7 I think the feeling is to leave the rest of it as is.
8 Richard, is that your understanding also?
9 DR. VETTER: Yes, that is my
10 understanding.
11 CHAIRMAN CERQUEIRA: Okay. John?
12 MR. HICKEY: Dr. Cerqueira, John Hickey.
13 I just wanted to clarify an important point with Dr.
14 Vetter that will apply to all the sections.
15 I want to clarify that it is the intent of
16 the Subcommittee that the boards that would be listed
17 would have to be evaluated against paragraph (b) and
18 meet paragraph (b) in order to continue to be listed.
19 DR. VETTER: This is Richard Vetter.
20 Yes, that is the intent of the
21 Subcommittee.
22 MR. HICKEY: Thank you.
23 DR. MALMUD: This is Malmud.
24 Going back to (b)(3), might the word
25 "statement" suffice instead of "certification"?

1 "Provide a written statement from a supervising
2 physicist" --
3 DR. VETTER: This is Richard Vetter.
4 I would certainly support the use of that
5 word.
6 CHAIRMAN CERQUEIRA: I think we will
7 probably have to get some idea from counsel on the
8 appropriateness, but on that I think everyone agrees
9 that maybe "certification" is too strong a word to put
10 in there, but "attestation" or some other appropriate
11 word or "a written statement" would be fine.
12 Okay, should we go on to 35.51, Training
13 for an Authorized Medical Physicist?
14 DR. DIAMOND: Excuse me, Dr. Cerqueira.
15 This is Dr. Diamond.
16 CHAIRMAN CERQUEIRA: Yes.
17 DR. DIAMOND: I was under the impression
18 we would be able to do the therapy sections first. I
19 have a fairly limited amount of time I can be on a
20 conference call today.
21 CHAIRMAN CERQUEIRA: You're right, that
22 had been requested. If no one else has any
23 objections, then why don't we do that?
24 DR. DIAMOND: So let's please direct our
25 attention to 35.390, which is the first section that

1 I worked on. This is Training for Use of Unsealed
2 Byproduct Material for Which a Written Record is
3 Required. This is about 5-d-iodine, which I will
4 address in a minute. I will give you a second to get
5 to 35.390.
6 For those of you who aren't familiar,
7 there is a parallel structure to all of these therapy-
8 related sections; simply, small paragraph (a)
9 addresses the board pathway. Small paragraph (b)
10 discusses the alternative pathway, and then small
11 paragraph (c) enumerates the boards that are listed.
12 So just to highlight the changes,
13 basically, small paragraph (a), this is indicating
14 that there must be successful completion of a
15 residency program, either radiation oncology or
16 nuclear medicine.
17 Paragraph (b) is essentially exactly the
18 same.
19 DR. MALMUD: Dr. Diamond?
20 DR. DIAMOND: Yes?
21 DR. MALMUD: This is Leon Malmud.
22 May I ask a question about --
23 DR. DIAMOND: Yes, sir.
24 DR. MALMUD: -- that paragraph? It says
25 -- this is Section (a)(1).

1 DR. DIAMOND: Yes, sir.

2 DR. MALMUD: "A minimum three-year

3 residency program in nuclear medicine." Now what

4 would happen to a radiologist who is board-certified

5 in radiology and a one- or two-year program in nuclear

6 medicine to augment that and become certified? Would

7 that qualify as a three-year program?

8 DR. DIAMOND: My understanding, Leon, is

9 that a radiologist who is currently board-certified in

10 practice would be grandfathered from these changes.

11 DR. MALMUD: Thank you.

12 DR. DIAMOND: And I'm sorry, small

13 paragraph (c) is just my attempt to enumerate the

14 boards in nuclear medicine or radiation oncology

15 currently recognized by the Commission. As Dr. Hickey

16 just mentioned, in all these sections, of course, the

17 staff would go back and assure that all the paragraph

18 (b) requirements were met by that particular board

19 before they were included in the regulation.

20 So I would be appreciative to hear the --

21 oh, by the way, Ralph, I noticed that on the

22 alternative pathway, I used the word "attestation" for

23 you.

24 MR. LIETO: Right.

25 DR. DIAMOND: Okay. At least it would be

1 good to hear any comments from those folks who weren't
2 on this working group or Subcommittee, please.
3 DR. WILLIAMSON: Jeff Williamson.
4 The currently-published training and
5 experience requirement lists as a requirement 12 cases
6 of iodine greater and less than 30 millicuries, and I
7 have forgotten what the other two categories are. But
8 you've dropped that out?
9 DR. DIAMOND: I used what I thought was
10 the currently-recommended language. Jeff is referring
11 to paragraph small (b), capital (G), where there are
12 four subsections of 1, 2, 3, and 4.
13 DR. WILLIAMSON: Here they are, yes.
14 DR. DIAMOND: And they are enumerated
15 there for you, Jeff.
16 DR. WILLIAMSON: Yes, but I guess the
17 question is, do you think that --
18 DR. DIAMOND: That was supposed to be
19 verbatim from what's --
20 DR. WILLIAMSON: Yes, I know that there,
21 but my comment is that one could get through, you
22 know, be board-certified in radiation oncology, have
23 come through a program where they didn't even do one
24 radionuclide application, and be an authorized user
25 for this.

1 I am wondering if it wouldn't be wise to
2 take the paragraph small (b)(1)(G), 1 through 4, and
3 put it as a separate section and say, regardless of
4 which of the three pathways you come from, a listed
5 board, a new board to be vetted in the future, or
6 alternative pathway, you need to do these 12 cases.
7 DR. DIAMOND: Right, that's one option.
8 The other option is simply to say that any doctor
9 coming on staff to a medical center who wishes to go
10 and have a specific privilege -- let's say you're a
11 radiation oncologist and in your training you've never
12 used radioactive iodine. Well, in that case you would
13 have to go, when you apply for privileges and they
14 will ask you, "Have you done this," and you say, "No,"
15 then you will not be granted privileges for that
16 particular submodality. That is the more
17 straightforward way to handle it, in my opinion.
18 MR. LIETO: This is Ralph Lieto.
19 Dr. Diamond, I kind of agree with Dr.
20 Williamson because my concern is that -- and correct
21 me if I am wrong -- but most radiation oncology
22 residencies don't involve the unsealed
23 radiopharmaceutical end of therapy. How would, say,
24 someone applying to the NRC, how would they know
25 whether their training program included

1 radiopharmaceutical therapies?

2 DR. DIAMOND: Well, Ralph, there is a

3 tremendous disparity in radiation oncology programs.

4 I can't give you a breakdown --

5 MR. LIETO: Okay.

6 DR. DIAMOND: -- but I would say it is a

7 50/50 mix. I have no specific objections in principle

8 to changing this around to be more prescriptive, in

9 other words, to tell the American Board of Radiology,

10 Section of Radiation Oncology, that they must go and

11 meet requirements 1 through 4 to grant board

12 certification.

13 DR. WILLIAMSON: No, I didn't say that,

14 David. I'm sorry, this is Jeff Williamson again. I

15 said that an authorized user is one who is certified

16 by the American Board of Radiology and Radiation

17 Oncology or some other board for nuclear medicine or

18 has this following alternative experience.

19 The last paragraph would be, "In addition

20 to the above paragraphs (a) through (b), an authorized

21 user for radiopharmaceutical therapy should have this

22 distribution of case experience."

23 DR. DIAMOND: And what I would propose,

24 Jeff, is I would go and add simply a small paragraph

25 (d), as in "dog," which we have done in other therapy-

1 related sections. Basically, again, to remind you of
2 the structure, small paragraph (a) is the board
3 pathways; small paragraph (b) is the alternative
4 pathway; small paragraph (c) is the currently-
5 recognized or is enumerated, and small paragraph (d)
6 would be basically a notation or a specification that
7 certain specific modality training for that particular
8 area in which they wish to function must also be
9 present, regardless of their board certification.
10 DR. WILLIAMSON: That's essentially what
11 I was suggesting.
12 MR. LIETO: Yes, this is Ralph Lieto. I
13 thought that's what Jeff said, too, because I would
14 agree with that, Dr. Diamond. I think that would
15 answer at least my concerns because, knowing that
16 someone was board-certified in radiation oncology, yet
17 had no unsealed source experience, and yet got
18 approved for that, I think it is just a disaster
19 waiting to happen.
20 DR. DIAMOND: As I think this proves, Jeff
21 and Ralph, this may be a very clear way to proceed,
22 and it would bring it in parallel, for example, with
23 Section 35.690, which is simply exactly that. For any
24 specific modality with which you wish to work, you
25 must have training experience in that specific

1 modality.
2 CHAIRMAN CERQUEIRA: This is Manuel
3 Cerqueira.
4 I think that would solve, though, the
5 problem. Really it almost sounds like (2)(E)(1), the
6 Radiation Safety Officer requirement, where we try to
7 put some more specific training requirements in there.
8 So, Ralph, you are happy with that?
9 MR. LIETO: Yes. This is Ralph Lieto. I
10 would agree with that.
11 DR. WILLIAMSON: Jeff Williamson. I think
12 also it is a less radical restructuring of this part,
13 so less likely to provoke a negative response from the
14 regulated community.
15 DR. MALMUD: Leon Malmud. I agree.
16 CHAIRMAN CERQUEIRA: Any other comments
17 from other members of the Committee?
18 DR. VETTER: This is Richard Vetter. I
19 agree as well.
20 CHAIRMAN CERQUEIRA: Okay.
21 MS. SCHWARTZ: Sally Schwartz. I agree
22 also.
23 DR. BRINKER: This is the other Jeff. I
24 agree.
25 CHAIRMAN CERQUEIRA: All right, so, David,

1 I think if we add that small (d) at the end --
2 DR. DIAMOND: Would you like me to move
3 onto the next two sections --
4 CHAIRMAN CERQUEIRA: I'm sorry, what?
5 DR. DIAMOND: Would you like me to move
6 onto the next two sections?
7 CHAIRMAN CERQUEIRA: Yes.
8 DR. DIAMOND: The next two sections,
9 35.392 and .394, respectively, have to do with the use
10 of sodium I-131; we find these less than or greater
11 than 33 millicuries, respectively. Basically, all
12 that was done is a competency statement was removed.
13 As was mentioned earlier, there was a very
14 strong sense by the Subcommittee that it is not
15 appropriate to have a preceptor attest to competency.
16 Therefore, I simply removed the competency statement
17 for both of those two sections and left the remainder
18 of the sections unchanged.
19 CHAIRMAN CERQUEIRA: Except we may want to
20 change some of that to "written statement" instead of
21 "certification." Ralph, would that be in line with
22 your earlier comment?
23 DR. MALMUD: You're referring now to
24 Sections 35.392 and 35.394?
25 CHAIRMAN CERQUEIRA: Right.

1 DR. MALMUD: Agreed. Malmud.

2 CHAIRMAN CERQUEIRA: Okay. Any further

3 discussion on these sections then?

4 DR. VETTER: This is Richard Vetter.

5 So did we decide to not use the word

6 "written certification" but something else a little

7 less strong, or what did we -- is that a theme we want

8 to follow in this whole section?

9 DR. EGGLI: I understood so then,

10 "attestation" or "statement."

11 MS. McBURNEY: "Notation."

12 DR. VETTER: Okay, so we will find a new

13 word for that.

14 CHAIRMAN CERQUEIRA: Okay.

15 MR. LIETO: This is Ralph Lieto.

16 On the copy here it doesn't have what the

17 hour requirement -- is there still the hour

18 requirements?

19 DR. DIAMOND: Everything is exactly the

20 same, Ralph, other than the removal of the competency

21 statement.

22 CHAIRMAN CERQUEIRA: Okay, any further

23 discussion on .392 and .394?

24 (No response.)

25 Again, if people have, you know, late,

1 late thoughts about some of these issues, they can
2 still send us written comments while the staff is
3 reviewing some of these changes.
4 Shall we go to 35.490?
5 DR. DIAMOND: Okay, 35.490 is Training for
6 the Use of Manual Brachytherapy Sources. This we did
7 not discuss in our June meeting. Basically, what I
8 have done is I have gone back and made it parallel in
9 structure to 35.690, which we did, in fact, discuss at
10 great length. So, once again, there is that format of
11 a board pathway, small paragraph (a); an alternative
12 pathway, small paragraph (b), and the small paragraph
13 (c), which is the enumeration of boards.
14 The only really changes in this whole
15 section is just, again, listing the residency
16 programs. Paragraph (a) continues also the residency
17 program director's statement attesting that the
18 training requirements have been met.
19 The examination, the hours on paragraph
20 (b), both for work experience and classroom experience
21 are unchanged.
22 DR. WILLIAMSON: Now (b) handles
23 alternative pathway, correct?
24 DR. DIAMOND: Correct, Jeff.
25 DR. WILLIAMSON: Okay.

1 MS. McBURNEY: This is Ruth.
2 This is the 20-hour requirement for manual
3 brachytherapy?
4 DR. DIAMOND: It is 200 hours of classroom
5 and laboratory.
6 MS. McBURNEY: Yes.
7 DR. DIAMOND: That's paragraph small (b)
8 on little Roman numeral (i), and then right after that
9 is 500 hours of work experience.
10 MS. McBURNEY: Right.
11 DR. DIAMOND: So that is unchanged.
12 Again, this was simply reworded to be parallel with
13 .690.
14 DR. WILLIAMSON: Could I just make a
15 comment about the sort of style of paragraph (a), I
16 guess? It is not really a substantive comment.
17 Jeff Williamson speaking.
18 DR. DIAMOND: Okay.
19 DR. WILLIAMSON: I wrote the --
20 DR. DIAMOND: The Williamson manual style.
21 (Laughter.)
22 DR. WILLIAMSON: Yes, right. To me,
23 paragraph (a) is not terribly clear that the board has
24 to meet features or has to exhibit features 1 through
25 4.

1 To give you an example, I wrote it in the
2 physicist part as, "if certified by a specialty board
3 in radiation oncology, certification has been
4 recognized by the Commission and requires all
5 diplomates," and then bang, bang, bang, bang, and it's
6 very clear that the 1 through 4 then are essential
7 features of a recognizable board, or one recognizable
8 by the Commission.
9 So it is just an issue of how it is
10 phrased rather than substantive.
11 DR. VETTER: This is Richard Vetter.
12 I actually support what Jeff just said.
13 If you moved those few words out of paragraph (a)(1)
14 into the major paragraph, then you eliminate room for
15 argument about whether 2, 3, and 4 go along for it or
16 if they are separate.
17 DR. DIAMOND: That is an easy fix.
18 CHAIRMAN CERQUEIRA: This is Manual
19 Cerqueira.
20 Any other comments on those changes that
21 have been proposed by Jeff and Richard?
22 MR. LIETO: This is Ralph Lieto.
23 I have one point for clarification. Under
24 the alternative pathway, (b), at the end of No. 2 you
25 say that the "experience may be obtained concurrently

1 with the supervised work experience." Did you want
2 that to state paragraph (b)(1)(ii) or did you just
3 want it to be (b)(1)? In other words, do you want the
4 700 hours to be concurrently with the three years of
5 supervised experience? Because right now you are just
6 saying the 500.
7 DR. DIAMOND: Oh, I see.
8 MR. LIETO: I think your intent is to have
9 just --
10 DR. DIAMOND: It is a lot clearer just
11 (b)(1).
12 MR. LIETO: Yes, drop the Roman numeral --
13 DR. DIAMOND: Well, that last sentence is
14 referring specifically to the supervised work
15 experience --
16 MR. LIETO: Right.
17 DR. DIAMOND: -- which is that paragraph
18 small Roman numeral (ii). Small Roman numeral (i) is
19 all classroom/laboratory time, Ralph.
20 MR. LIETO: Okay. Well, I'm just checking
21 for clarification. Did you want the classroom
22 experience to be also concurrent with the supervised
23 -- you know, with the three years of clinical
24 experience? In other words, I guess what I am asking
25 is, couldn't you or wouldn't most programs have their

1 classroom and work experience as a part of the three
2 years with the residency program?
3 I don't have a strong opinion one way or
4 the other, but I just wanted to be sure that --
5 because what it sounds like here, you've got to have
6 200 hours plus three years of supervised experience.
7 That is what I am interpreting that to mean right now,
8 and I don't know if that was the intent.
9 DR. DIAMOND: Other thoughts on that?
10 DR. VETTER: This is Richard Vetter.
11 I agree with Ralph's interpretation. I
12 didn't catch that either, but normally the lectures,
13 and so forth, that the residents receive, they would
14 receive during that three years of residency, wouldn't
15 they?
16 DR. DIAMOND: Okay, so we could go and
17 change that to (b)(1) alone --
18 DR. VETTER: Right.
19 DR. DIAMOND: -- and delete that small
20 Roman numeral (ii).
21 MS. McBURNEY: This is Ruth McBurney.
22 With the "this experience may be obtained
23 concurrently with the" --
24 DR. DIAMOND: Training?
25 MS. McBURNEY: -- "training and supervised

1 work experience required by paragraph (b)(1)."

2 DR. DIAMOND: Yes.

3 MS. McBURNEY: Or (b) --

4 DR. DIAMOND: (b)(1).

5 MS. McBURNEY: (b)(1), right.

6 DR. WILLIAMSON: Jeff Williamson. I

7 support this, too.

8 MS. SCHWARTZ: Sally Schwartz. I agree

9 that sentence is to clarify.

10 DR. MALMUD: Malmud. Agree.

11 CHAIRMAN CERQUEIRA: So I think there is

12 pretty much agreement.

13 There's been a couple of comments that

14 have been made if perhaps under this .490 we should

15 also include a paragraph similar to what we have on

16 the .690, which is the last (d), which basically tries

17 to -- will give training in a specific modality for

18 which authorized use is being sought,

19 DR. DIAMOND: I thought about that when I

20 was working on this, and I didn't think that there was

21 enough -- this is such a specific section. This is

22 Manual Brachytherapy Sources and so specific that I

23 can't imagine that there is enough differences in

24 modality, or whatnot, to justify a paragraph (b). It

25 is already such a narrow field, if you will.

1 CHAIRMAN CERQUEIRA: Okay, how does the
2 rest of the Committee feel about --
3 DR. WILLIAMSON: Well, this is Jeff
4 Williamson.
5 I do believe that the Accreditation
6 Committee for Radiation Oncology requires minimum
7 caseload in general brachytherapy as a condition of
8 being an approved program. Is that not true, David?
9 DR. DIAMOND: Yes, that is correct. This
10 is one of the areas where you must go and enumerate
11 the number of cases that you have done to meet basic
12 -- to become board-certified.
13 DR. WILLIAMSON: So I guess I would submit
14 the proposition that I think the residency, even
15 minimal residency in radiation oncology, includes
16 adequate clinical experience and hands-on training
17 with forms of manual brachytherapy. I agree with Dr.
18 Diamond that a special modality-specific competence
19 really isn't meaningful.
20 CHAIRMAN CERQUEIRA: For manual
21 brachytherapy. Richard, do you have any comments,
22 Richard Vetter?
23 DR. VETTER: No, I agree with David and
24 Jeff's interpretation that we do not need that
25 specific paragraph or paragraph on specific modalities

1 for this section.

2 CHAIRMAN CERQUEIRA: Okay, other comments

3 from the Committee?

4 (No response.)

5 Now we had one comment from the audience

6 here at NRC headquarters in Rockville. Bill Uffelman?

7 Okay, no, we have answered it.

8 Okay, so how does the Committee feel?

9 They're happy with .490 as modified?

10 DR. VETTER: This is Richard Vetter. I'm

11 happy with it.

12 MS. SCHWARTZ: Sally Schwartz. I'm happy

13 with the modification.

14 CHAIRMAN CERQUEIRA: Okay.

15 DR. MALMUD: Malmud. Content.

16 MS. McBURNEY: This is Ruth. Sounds good

17 to me.

18 DR. BRINKER: Brinker. It's fine with me.

19 MR. LIETO: Ralph Lieto. It's okay with

20 me.

21 DR. EGGLI: Eggli. Okay.

22 CHAIRMAN CERQUEIRA: All right, so then I

23 think we are finished with .490.

24 DR. DIAMOND: Okay, why don't we go to

25 35.491?

1 CHAIRMAN CERQUEIRA: Okay.
2 DR. DIAMOND: This is, again, an example
3 of just simply removing a competency statement, to be
4 parallel with what we were doing earlier. This is for
5 the ophthalmic use of strontium-90 for, for example,
6 the prevention of traechia, and so forth.
7 Simply, if you look at a competency
8 statement, again, we could go and change the wording
9 from "certification" or "attestation," or whatever we
10 would like.
11 CHAIRMAN CERQUEIRA: Yes, I think, again,
12 we will make that uniform across all of these
13 different modalities.
14 DR. DIAMOND: Okay, then we will go and
15 skip to 35.690, which is Training for Use of Remote
16 After-Loader Units, Teletherapy Units, and Gamma
17 Stereotactic Radiosurgery Units.
18 Once again, Colleagues, format is small
19 paragraph (a), boards pathway; small paragraph (b),
20 which is alternative pathway; small paragraph (c),
21 which is the currently-recognized boards, and small
22 paragraph (d), which is a modality-specific training.
23 Let's see, paragraph (a) will really be
24 exactly the same as what we just did for the manual
25 brachytherapy sources. So if there is any sense, once

1 again, that we should go and clarify paragraph (a) in
2 .490, we should do the same in this section, whatever
3 language Dick or Jeff wanted to recommend.
4 Paragraph (b)(1) is exactly the same.
5 Paragraph (b)(2) is the preceptor
6 statement. We can discuss, for example, on paragraph
7 (b)(2), just as we discussed a few moments ago, the
8 concurrent experience, should it apply both to Roman
9 numeral (i) and (ii) or just to Roman numeral (ii).
10 DR. WILLIAMSON: Yes, I would recommend
11 making the changes we discussed for 35.490 --
12 DR. DIAMOND: Okay.
13 DR. WILLIAMSON: -- to both paragraph (a)
14 and paragraph (b) to this section.
15 DR. DIAMOND: That's fine with me. So
16 what we would do is, again, change that last sentence
17 on paragraph (b)(2) to read, "This experience may be
18 obtained concurrently with the training and supervised
19 work experience required by paragraph (b)(1) of this
20 section."
21 DR. VETTER: This is Richard Vetter. I
22 support that change.
23 MS. SCHWARTZ: Sally Schwartz. I agree.
24 DR. DIAMOND: We spent a lot of time in
25 our June meeting on paragraph (d), thanks to Jeff's

1 help, which basically says that, for whatever specific
2 modality which you're choosing to seek authorization,
3 you must also have specific training in that
4 particular area. So that's a very important change
5 that we made.
6 CHAIRMAN CERQUEIRA: Any additional
7 comments or changes, disagreement with what has been
8 proposed?
9 MR. LIETO: This is Ralph Lieto. I have
10 a question for NRC staff in relation to this Section
11 (d).
12 The very last sentence says, "training
13 supervised by an authorized user or authorized medical
14 physicist, as appropriate, who is authorized for the
15 modality." The NRC, are the licenses going to list
16 the modalities that the physicist is authorized for?
17 MR. HICKEY: This is John Hickey.
18 Yes, it will be either in the license or
19 it will be clear from the application what activity
20 the medical physicist or authorized user is authorized
21 for.
22 MR. LIETO: Okay, thank you.
23 DR. WILLIAMSON: This is Jeff.
24 In redrafting 35.51 for the authorized
25 medical physicist, I tried to eliminate the ambiguity

1 in the wording that led to NRC staff's initial
2 conclusion that there could not be modality-specific
3 AMP.
4 CHAIRMAN CERQUEIRA: Okay, any further
5 discussions on this then or does the Committee agree
6 that this is acceptable as written with the changes
7 that have been proposed? Any disagreement on this,
8 rather than running around and getting people's
9 concurrence on it?
10 DR. WILLIAMSON: Well, this is Jeff
11 Williamson.
12 I think that at some point we will have to
13 -- maybe it won't be us; maybe it will be the staff --
14 will have to decide which language to use for hard-
15 wiring the boards, because now the diagnostic 35.190
16 and .290 have (a) "is certified in nuclear medicine by
17 American Board of Nuclear Medicine," et cetera, et
18 cetera. So the AMP is written in a similar way.
19 Dr. Diamond has proposed an alternative
20 way of seeding this which lists which boards are
21 currently recognized. So there is an asymmetry in the
22 language that at some point has to be straightened
23 out. All of the sections should be written one way or
24 the other.
25 CHAIRMAN CERQUEIRA: Okay, I would agree

1 with that. I think the staff will do so.

2 It has also been pointed out to me, if we
3 look at the last page in (d), in addition to meeting
4 the requirements of paragraphs (a) or (b), it should
5 also say, "or (c) of this section." I think that is
6 sort of implied.

7 All right, I think for 35.690, I think
8 there is general agreement on this.

9 DR. DIAMOND: Dr. Cerqueira,
10 unfortunately, I have to get going. I have some
11 patients waiting. I appreciate you allowing me to go
12 ahead with this therapy section.

13 CHAIRMAN CERQUEIRA: David, the one
14 section we didn't cover was 35.590.

15 DR. DIAMOND: Would that be diagnosis?

16 MS. McBURNEY: I had that one. This is
17 Ruth.

18 CHAIRMAN CERQUEIRA: Ruth has it, okay.
19 Okay, thank you, David.

20 DR. DIAMOND: My pleasure. Thank you very
21 much.

22 CHAIRMAN CERQUEIRA: All right. So we
23 have covered the therapy. I guess we can then go back
24 to 35.51, which is Training for Authorized Medical
25 Physicists, and Dr. Williamson.

1 DR. WILLIAMSON: Okay, this one is written
2 in a parallel fashion to the RSO and the authorized
3 user for full-time emitting devices. It says, "(a) an
4 authorized medical licensee shall require authorized
5 medical physicists to be an individual who is (a)
6 certified by one of the following specialty boards in
7 radiation oncology physics," and it lists them all,
8 "(b) is certified by a specialty board in radiation
9 oncology physics whose certification has been
10 recognized by the Commission and requires all
11 diplomates" -- it runs through a graduate degree from
12 an accredited institution to two years of full-time
13 practical training in radiation oncology physics, and
14 specifies that it actually has to be done in a
15 clinical facility providing external beam therapy and
16 some form of brachytherapy service.
17 "Obtains written certification," or I
18 guess maybe now "statement," "of physicists who are
19 certified by one of the recognized specialty boards as
20 to candidates satisfactorily completing the training
21 experience, and (4) passes an examination administered
22 by a diplomate."
23 Then (4) leads to Part (c), which is the
24 alternative pathway. This is very similar to what is
25 in the current regulation. I have tried to soften it

1 a little bit because I am afraid there may be some
2 people who want to use the alternative pathway, and so
3 few institutions have cobalt-60 teletherapy and not
4 that many have gamma stereotactic, that I tried to
5 liberalize it a little bit, so that there would be
6 more training facilities that would be eligible.
7 Then (d) is the modality-specific section.
8 In addition to meeting the requirements of (a), (b),
9 or (c) in this section, "an authorized medical
10 physicist must have training in the modality for which
11 authorization is sought." It lists the features
12 there.
13 The intent is to basically have the
14 mechanisms that are already used within the community
15 for training new physicists for these modalities,
16 would be able to comply with this sentence.
17 Okay, so that finishes my summary.
18 CHAIRMAN CERQUEIRA: All right, any
19 comments or suggestions? There's been a lot of work
20 on this.
21 MR. LIETO: Jeff, this is Ralph Lieto.
22 Just on part (c) there, where you have the
23 services in a task listed in those sections, do you
24 think that might be too prescriptive as opposed -- in
25 other words, do you want to list the subject matter as

1 opposed to the sections, or sections change in
2 content, and so forth? And just a thought, do you
3 think that would be a concern for future changes?
4 DR. WILLIAMSON: Yes, I thought about this
5 some, and the way I think it is written now is these
6 different sections, 35.643, and so forth, they make
7 reference to spotchecks and full calibrations of
8 stereotactic radiosurgery, high-dose-rate
9 brachytherapy, and cobalt-60 teletherapy. The intent
10 was to actually have experience with LINAC-based
11 external beam to qualify an applicant for doing
12 calibrations on a cobalt unit, since the basic
13 methodology is identical.
14 The only modality I thought was reasonable
15 to expect a facility to have is high-dose-rate
16 brachytherapy, which is now pretty pervasively
17 available in the community. It's certainly large
18 market penetration compared to the other two devices.
19 But we certainly could take out 35.67 and
20 put whatever it refers to, which is external beam full
21 calibrations and periodic spotchecks.
22 MR. LIETO: That would be my
23 recommendation simply because down the pike it may be
24 that people will, or it may be interpreted that they
25 have to be the task on that specific device. Do you

1 see what I'm saying?

2 DR. WILLIAMSON: Yes.

3 MR. LIETO: I don't think that was your

4 intent.

5 DR. WILLIAMSON: That's correct. I am

6 trying to get away from that.

7 MR. LIETO: I was thinking that maybe you

8 might want to list, just like you specified full

9 calibrations and periodic spotchecks, and the tasks

10 that are involved as opposed to the section, because

11 I think it is going to be interpreted that they have

12 to have the experience that satisfies that section,

13 which may be to the cobalt or whatever -- that's my

14 concern.

15 DR. WILLIAMSON: Well, I think that is a

16 reasonable change to make. I support that.

17 CHAIRMAN CERQUEIRA: Any other comments

18 for Dr. Williamson?

19 MS. McBURNEY: This is Ruth. I agree with

20 those changes, to list the tasks rather than specific

21 to Part 35, and make it a little plainer.

22 DR. WILLIAMSON: Yes, just so it is clear

23 to the staff and everyone, too, who is examining this,

24 the concept underlying this is that calibration and

25 quality assurance experience for LINACs is applicable

1 to cobalt-60 teletherapy. All of the operational
2 procedures that are used for LINAC-based stereotactic
3 radiosurgery I think give one very good general
4 qualifications for carrying out the same tasks for
5 cobalt-60 -- no, for gamma knife stereotactic
6 radiosurgery.
7 There is, in addition, Part (d) would
8 essentially require alternative pathway candidates as
9 well as board-certified candidates to have gone
10 through some kind of a training experience for the
11 specific device, which would redress any of the small
12 deficiencies or differences between their training
13 experience and what their current clinical duties will
14 be. That's the assumption.
15 MS. SCHWARTZ: I agree with what you are
16 saying, Jeff, also. This is Sally Schwartz.
17 CHAIRMAN CERQUEIRA: All right, I think
18 there is pretty good consensus that this is well-
19 written, Jeff.
20 Does anyone feel strongly that we should
21 have further discussion on this or are people in
22 general happy with the new language?
23 DR. VETTER: Vetter is happy.
24 DR. MALMUD: Malmud's content.
25 CHAIRMAN CERQUEIRA: Okay, good, then

1 excellent job, Jeff. You've persevered with this.

2 The next section is 35.55, Training for an

3 Authorized Nuclear Pharmacist. Sally, you were on the

4 Subcommittee, but who was responsible for this?

5 MS. SCHWARTZ: I was, the Authorized

6 Nuclear Pharmacist.

7 CHAIRMAN CERQUEIRA: Oh, you were? Okay.

8 MS. SCHWARTZ: Yes. Actually, I was

9 contacted by Dr. Vetter --

10 CHAIRMAN CERQUEIRA: Good.

11 MS. SCHWARTZ: -- actually followed

12 through with this section.

13 CHAIRMAN CERQUEIRA: Good, okay.

14 MS. SCHWARTZ: Essentially, there weren't

15 changes majorly in the new Part 35, but there were

16 comments that came up, I guess, in the workshop open

17 session. What I was asked to do is essentially define

18 an alternate pathway for another board, if there would

19 become one. Currently, for the board of pharmacy,

20 there is one national board, the American

21 Pharmaceutical Association, which board certifies

22 nuclear pharmacists.

23 So what I was asked to do is essentially

24 define what those qualities were, so that if in the

25 future another board would become available, that they

1 would have to meet the same requirements that are
2 already defined by the Board of Pharmaceutical
3 Specialties, which is what I did.
4 So, essentially, the (a) is that a
5 pharmacist be board-certified by the Board of
6 Pharmaceutical Specialties or (b) board-certified as
7 a nuclear pharmacist by a specialty board whose
8 certification process has been recognized by the
9 Commission, and then requires all diplomates to
10 essentially fulfill all the currently listed
11 requirements for board certification.
12 Something that comment-wise has come up
13 since I wrote this from Joel Hung, and I wanted to
14 raise this, rather than being as prescriptive as
15 listing all of these items, as I have done in (b), he
16 did provide a thought that maybe just a general
17 statement to the effect that says, "if certified as a
18 nuclear pharmacist by a specialty board whose
19 certification process includes all of the requirements
20 in paragraph (b)," which define the requirements for
21 licensure -- I guess it would be now (c) -- "of this
22 section, whose certification program should be
23 equivalent to that offered by the Board of
24 Pharmaceutical Specialties in Nuclear Pharmacy,
25 including the recertification process, or have been

1 recognized by the Commission or an Agreement State."
2 So I wanted to at least state that to this
3 group, and for myself either is acceptable, the
4 listing of what is currently required or the less
5 prescriptive statement that essentially any board, if
6 it would become available, that it would have to
7 comply.
8 MS. McBURNEY: This is Ruth McBurney.
9 I would prefer the way you have it here
10 with setting out the criteria for the Commission to
11 follow --
12 MS. SCHWARTZ: Right.
13 MS. McBURNEY: -- on approving any board.
14 I just had a quick question. Do the
15 Canadians have board certification? Do you know?
16 MS. SCHWARTZ: I am not aware that they do
17 or not, but there is an omission from this that
18 actually has a reflection on what your question is in
19 the Board Candidate's Guide for the current Board of
20 Pharmaceutical Specialties.
21 In No. 1 they actually state that, "has
22 graduated from a pharmacy program accredited by the
23 American Council on Pharmaceutical Education or an
24 alternative educational program accepted by EST." So
25 there are other programs available outside the United

1 States that are acceptable pathways for licensure,
2 board certification. So I would like that written
3 into this No. 1.
4 DR. VETTER: This is Richard Vetter.
5 Sally, is there a way to make that more
6 generic? Rather than an alternative program
7 acceptable to the Board of Pharmaceutical
8 Specialties --
9 MS. SCHWARTZ: Yes, okay, so we could not
10 list that, but --
11 DR. VETTER: No.
12 MS. McBURNEY: Okay.
13 MR. HICKEY: Please speak up.
14 MS. McBURNEY: Oh, I was kind of mumbling
15 to myself. All right, this is Ruth. I am trying to
16 think of some alternate language.
17 DR. VETTER: This is in (b)(1)?
18 MS. McBURNEY: (b)(1).
19 DR. VETTER: And the intent of the
20 language is just to recognize --
21 MS. SCHWARTZ: Alternative educational
22 programs, and these are outside of the United States.
23 DR. VETTER: Okay.
24 MS. SCHWARTZ: Because there are those
25 candidates that come in with acceptable educational

1 programs; they still, then, apply with that
2 training --
3 DR. VETTER: To the Board?
4 MS. SCHWARTZ: Yes, correct.
5 DR. VETTER: Well, yes, somehow it seems
6 -- so what is the criterion that the Board uses for
7 eligibility?
8 MS. SCHWARTZ: Now what board?
9 DR. VETTER: Well, when the Board -- when
10 applicants come before the Board --
11 MS. SCHWARTZ: From another country?
12 DR. VETTER: -- of Nuclear Pharmacy, Board
13 of Pharmaceutical Specialties and Nuclear Pharmacy --
14 MS. SCHWARTZ: Correct.
15 DR. VETTER: -- and they have some
16 applicant from a foreign pharmacy school, what is
17 their criterion for accepting it?
18 MS. SCHWARTZ: All of the listed items,
19 essentially. So that it could be an alternate
20 educational program including all the listed
21 requirements.
22 CHAIRMAN CERQUEIRA: Under (c).
23 MS. SCHWARTZ: Of (b) in this section.
24 DR. VETTER: Well, there aren't any, I
25 don't see any requirements for the educational program

1 here, other than it is accredited by the American
2 Council on Pharmaceutical Education.
3 MS. SCHWARTZ: Well, essentially, the
4 2,000 hours academic, the 4,000 hours of
5 training/experience in nuclear pharmacy practice, and
6 essentially then the passing grade on a board
7 certification exam, those types of requirements.
8 MS. McBURNEY: This is Ruth again.
9 DR. VETTER: I'm confused now.
10 MS. McBURNEY: I was wondering if we could
11 use parallel language to some of these others, that
12 board certification includes diplomates who graduated
13 from -- for example, a medical physicist is from an
14 institution accredited by a regional accrediting body.
15 MS. SCHWARTZ: Yes, that would be
16 acceptable.
17 DR. WILLIAMSON: Yes, I think the
18 qualification needs to be put into (b)(1). It is a
19 qualification for the degree, and you have 2, 3, and
20 4 as separate requirements. So I think the person
21 obviously has to show evidence that he has the 4,000
22 hours of training experience or additional education.
23 I understood your question, Sally, to be
24 one of, how do you identify appropriate educational
25 degree-granting programs are acceptable for No. 1, for

1 No. (b)(1) only?

2 MS. SCHWARTZ: That is correct. That is

3 correct.

4 DR. WILLIAMSON: So you have to find a

5 statement for that that probably doesn't make

6 reference to 2, 3, and 4 --

7 MS. SCHWARTZ: Correct.

8 DR. WILLIAMSON: -- which are other

9 components.

10 MS. SCHWARTZ: Those are additional

11 components required.

12 DR. WILLIAMSON: Yes.

13 MS. SCHWARTZ: Right. The alternative

14 educational program accepted, rather than by the Board

15 of Pharmaceutical Specialties, accepted --

16 DR. WILLIAMSON: Yes, so the question is,

17 when the Board looks at candidates who comes from

18 these different programs and looks just at the

19 academic program component of their credentials, what

20 is their criterion for accepting it as a good program

21 versus the bad program?

22 MS. SCHWARTZ: Well, that's review, I'm

23 assuming, of the educational requirement for the

24 pharmaceutical program at the universities in the

25 alternate country, similar academic, essential six-

1 year training program, not that necessarily they list
2 that six-year requirement, but it is a six-year
3 degree-granting program in the United States.
4 So I am not certain how they have
5 evaluated those criterion. I could get a hold of
6 them.
7 DR. WILLIAMSON: Maybe it would be worth
8 looking into it.
9 MS. SCHWARTZ: Yes. All right, I will do
10 that.
11 DR. WILLIAMSON: Because I don't think we
12 want to exclude a pool of qualified candidates from
13 abroad --
14 MS. SCHWARTZ: Right.
15 DR. WILLIAMSON: -- if the whole industry
16 depends on them; it would be a bad mistake.
17 MS. SCHWARTZ: What I could essentially do
18 is get this information and then report back to -- who
19 would be the appropriate individual in this group that
20 I would report back to as far as finalizing this
21 section?
22 MR. HICKEY: This is John Hickey.
23 First of all, I wanted to mention that Dr.
24 Cerqueira was paged, so he had to step away from a
25 moment, and he asked that we continue.

1 Dr. Vetter, I think that they should get
2 back to you with the changes.
3 MS. SCHWARTZ: Okay.
4 MR. HICKEY: Does Dr. Vetter agree with
5 that?
6 DR. VETTER: Dr. Vetter agrees with that.
7 MR. HICKEY: Okay.
8 MS. SCHWARTZ: All right. Dr. Vetter, I
9 will get the information back to you then. I will not
10 be back to St. Louis for a week. Is that acceptable?
11 DR. VETTER: That is acceptable to me. Is
12 it acceptable to the NRC relative to their timeline?
13 MR. HICKEY: Well, we want to wrap this up
14 as soon as we can, but you could go ahead and submit
15 that. If there's still a piece that is missing, we
16 could handle that later.
17 DR. VETTER: Okay.
18 MR. HICKEY: But I wouldn't want the whole
19 thing to be held up because of that.
20 DR. VETTER: Right.
21 MS. SCHWARTZ: Right. I will still send
22 it to you in a week.
23 DR. VETTER: Okay.
24 MS. SCHWARTZ: All right?
25 Additionally, for this section,

1 essentially, this Part (c) is completion of the 700
2 hours; (b) structured educational program, essentially
3 defining the alternate pathway consisting of didactic
4 training. It provides practical training.
5 And, No. 3, then, having obtained "written
6 attestation signed by a board-certified nuclear
7 pharmacist or a preceptor authorizing that an
8 individual has completed the required training listed
9 in (b)(2) of this section." So certifying just the
10 training, not the educational material.
11 DR. MALMUD: Malmud. May I ask a
12 question? How many authorized nuclear pharmacists are
13 there in the United States?
14 MS. SCHWARTZ: About 490.
15 DR. MALMUD: Do you regard that number as
16 being adequate to further certify other individuals?
17 MS. SCHWARTZ: This can also be -- it
18 doesn't require that the training be authorized by an
19 authorized nuclear pharmacist; they can be by an AMP
20 or board-certified, yes, nuclear pharmacist.
21 DR. MALMUD: So there would be more than
22 ample ways of individuals becoming --
23 MS. SCHWARTZ: Correct.
24 DR. MALMUD: Okay. Thank you.
25 DR. WILLIAMSON: This is Jeff. I have

1 another question.

2 Where did the 700 hours come from, and
3 what was the intent behind that? There seems to be a
4 rather large disparity between the training and
5 experience requirements of the Board versus its
6 alternative pathway.

7 MS. SCHWARTZ: That was written prior. I
8 did not change that. That was what was listed as the
9 alternate training hours, and I was not involved in
10 the writing of that section. I assumed that what my
11 task was essentially was to define what a board, if
12 there were to be another board defined in the United
13 States, what those qualifications should be for
14 essentially a new board.

15 But now the alternate pathway was defined.
16 I did not define that.

17 DR. VETTER: This is Richard Vetter.

18 The scope of our charge did not include
19 addressing the alternate pathway except for the issue
20 of preceptor statement.

21 MS. SCHWARTZ: And in that case the
22 preceptor statement is just that the preceptors sign
23 or attest to the training, but not the didactic
24 training.

25 CHAIRMAN CERQUEIRA: This is Manuel

1 Cerqueira. I think that 700 hours is very similar to
2 what we have in the therapies sections as well as in
3 the diagnostic studies as well.
4 You know, we had some discussions when
5 Dennis Swanson sat on the Committee. I think people
6 felt comfortable with the hourly requirements in the
7 didactic and the supervised training. I would be in
8 favor of keeping that in.
9 MS. SCHWARTZ: I agree with that. It was
10 Dennis Swanson who was involved in that portion of the
11 regulation, and I am in favor of maintaining that as
12 700 hours.
13 CHAIRMAN CERQUEIRA: Are there other
14 comments?
15 MR. LIETO: This is Ralph Lieto.
16 Sally, I have a question on the Section
17 (b) there. I am a little confused by the 1,500 credit
18 hours. It talks about undergraduate and post-
19 graduate.
20 MS. SCHWARTZ: Correct.
21 MR. LIETO: Are those supposed to be hours
22 of -- I'm trying to think, God, these people are going
23 to be in there forever.
24 MS. SCHWARTZ: Fifteen hundred hours, and
25 it should probably not say "of credit," but just of

1 hours.

2 MR. LIETO: Okay.

3 MS. SCHWARTZ: As it is written above, it

4 is a maximum of 2,000 hours can be obtained

5 academically by undergraduate courses. Up to a

6 maximum of 1,500 hours credit can be obtained under

7 certain undergraduate courses.

8 MR. LIETO: So then that is not supposed

9 to be "credit hours," --

10 MS. SCHWARTZ: No.

11 MR. LIETO: -- but they go towards that

12 2,000 total?

13 MS. SCHWARTZ: Correct. That is correct.

14 So those words could be removed.

15 MR. LIETO: Okay. It is also in (c) and

16 (d), too.

17 Now in (d) it says 220 hours of credit.

18 Is that correct?

19 MS. SCHWARTZ: That's right, and the way

20 that the current Board of Pharmaceutical Specialties

21 -- actually, I semi-modified this (b). They actually

22 have two programs. Dr. Vetter directed me to -- I had

23 listed them previously. One is the University of New

24 Mexico program, and the other is Purdue University.

25 I think Purdue -- I'm sorry, Purdue and Oklahoma have

1 two programs, and they allow one 210 and the other, I
2 think it's 217, and we can just take it to 200, if you
3 want, but I just kind of rounded it up to 220 hours.
4 That has been defined by the Board for these
5 individual programs. So I left it as a maximum of
6 220.
7 MR. LIETO: Okay.
8 MS. SCHWARTZ: It seems like an odd
9 number, but that is written in the Guide for the Board
10 of Pharmaceutical Specialties. I can read you their
11 actual language. I will get it.
12 CHAIRMAN CERQUEIRA: Other comments for
13 Sally?
14 MS. SCHWARTZ: I can just reiterate the
15 actual statement in there. They are listing it as
16 "successful completion of the nuclear pharmacy
17 certificate program offered by Purdue University,
18 which is 217 hours, or the Ohio State University, 214
19 hours. Credit for all other courses will be assessed
20 on a case-by-case basis. So I just left it as a more
21 generic 220 hours.
22 Should I add possibly that, of course, it
23 would be accreditation on a case-by-case basis?
24 DR. EGGLI: Well, would you reject the
25 board that refused to look at these other programs on

1 a case-by-case basis?

2 MS. SCHWARTZ: Well, I mean, it should be

3 looked at on a case-by-case basis.

4 DR. EGGLI: Well, I'm not arguing what the

5 current Board has decided to do, whether it is wise or

6 not, but these are supposed to be criteria for --

7 MS. SCHWARTZ: Right, for new --

8 DR. EGGLI: -- for new programs. So it

9 seems to me you wouldn't be giving up very much to

10 simply delete that, if it is confusing or difficult to

11 enforce.

12 MS. SCHWARTZ: Right.

13 DR. EGGLI: So what if a program comes

14 along that has 4,000 hours but doesn't look at those

15 ones? Does it really matter? It seems that it is

16 such a small thing that --

17 MS. SCHWARTZ: That's true. That's true.

18 DR. EGGLI: You know, rather than exactly

19 put down the precise board requirements, you really

20 want to capture the essence --

21 MS. SCHWARTZ: Yes.

22 DR. EGGLI: -- of what makes your board

23 the way it is.

24 MS. SCHWARTZ: I agree. For that purpose,

25 (b) could actually be omitted, if that would make

1 it --

2 DR. EGGLI: Less confusing.

3 MS. SCHWARTZ: -- less confusing.

4 CHAIRMAN CERQUEIRA: Yes, I think that

5 would help.

6 MS. SCHWARTZ: All right.

7 CHAIRMAN CERQUEIRA: So it would eliminate

8 1 actually through (d)?

9 MS. SCHWARTZ: Yes.

10 CHAIRMAN CERQUEIRA: Okay. Are there

11 other comments? I guess we could probably send

12 another draft of this portion on because I have to

13 admit I didn't look at it that closely. I think some

14 of the suggestions would sort of simplify it and give

15 us the intended results without making it too

16 restrictive.

17 Richard, any other changes?

18 DR. VETTER: This is Richard Vetter.

19 No, I think these suggestions are

20 excellent. When Sally revises the section, including

21 adding those words under (b)(1), I will make sure that

22 the new section in its entirety gets referred to the

23 Committee, the entire Committee, for an additional

24 look.

25 CHAIRMAN CERQUEIRA: Okay, great. Shall

1 we go on to 35.190, Training for Uptake Dilution and
2 Exclusion Studies?
3 MS. McBURNEY: This is Ruth McBurney. I
4 had that one.
5 This is the first of the series of
6 authorized user requirement. What I did on this was
7 the hard-wiring and back in the boards that had been
8 accepted by the Commission in the past, and for
9 parallel structure changed what the preceptor signed
10 as just attesting to the satisfactory completion of
11 the training requirement, training experience of 60
12 hours.
13 We also added in that, if that training is
14 received in conjunction with a residency program, that
15 written -- I guess we're changing it to "attestation,"
16 or whatever -- could be signed by the residency
17 program director.
18 So those are the basic changes that were
19 made from the new Part 35.
20 CHAIRMAN CERQUEIRA: I think there was
21 fairly good agreement at the Subcommittee meeting on
22 these changes.
23 Any other comments?
24 DR. WILLIAMSON: This is Jeff Williamson.
25 I think in Section (b)(2), someone

1 commented on my section that instead of having written
2 and oral exams, one should just have an examination,
3 because some of the boards are talking about going to
4 computer-administered exams and such, and that it
5 seems unnecessarily detailed and prescriptive to
6 specify both written and oral components.
7 DR. VETTER: This is Richard Vetter.
8 I think that the comment is an accurate
9 reflection of a discussion that occurred during
10 Committee. Somehow we have overlooked that. But I
11 agree, we did intend to make that a little bit more
12 generic.
13 MS. McBURNEY: So we would be taking out
14 "written and oral" and it would just be "required
15 successful completion with a passing grade of exam" --
16 DR. WILLIAMSON: Of an examination, yes.
17 MS. McBURNEY: -- "examination."
18 DR. VETTER: Yes, an examination.
19 MR. LIETO: Ralph Lieto. Are "successful
20 completion" and "with a passing grade" redundant?
21 DR. VETTER: Yes, yes, take off
22 "successful." That also was a comment that we had
23 earlier.
24 MS. McBURNEY: Okay.
25 DR. WILLIAMSON: And then the next

1 question is on (b)(3). Some of the sections say,
2 "board recognized by a Commission" and some say, this
3 one says, yours, Ruth, says, "by the Commission or an
4 Agreement State."
5 MS. McBURNEY: Right, I had just forgotten
6 to take that out.
7 DR. WILLIAMSON: Okay, so "by the
8 Commission" then --
9 MS. McBURNEY: By the Commission.
10 DR. WILLIAMSON: -- is what you intend?
11 The idea was several people commented on my strawman
12 T&E that they thought that the recognition process
13 should somehow be centralized.
14 MS. McBURNEY: Right, at the Board.
15 DR. WILLIAMSON: Yes, the board
16 recognition process.
17 MS. McBURNEY: But for (c), if they are
18 already on an Agreement State license --
19 DR. WILLIAMSON: No, that's okay, I think.
20 MS. McBURNEY: .290 or .390, yes; then
21 they can do the .190 stuff.
22 DR. WILLIAMSON: Yes, I think so.
23 MS. McBURNEY: All right.
24 DR. WILLIAMSON: It was only (b)(3) I was
25 talking about.

1 MS. McBURNEY: Yes, I had just failed to
2 take that out, and the same way on .290 as well.
3 DR. WILLIAMSON: Exactly.
4 MS. McBURNEY: Right. Corrections there,
5 too. Okay.
6 Is that it for .190?
7 CHAIRMAN CERQUEIRA: Other comments for
8 this?
9 DR. MALMUD: Not from Malmud.
10 CHAIRMAN CERQUEIRA: Okay, then let's go
11 on to .290.
12 MS. McBURNEY: Okay. For .290, this is
13 for Energy and Localization Studies. We hard-wired in
14 the boards that have been accepted, including the one
15 that the Commission has recently accepted, and that is
16 the Certification Board of Nuclear Cardiology.
17 Then, likewise, on (b) we will make the
18 same changes in (2) about the examination, and in (3)
19 correcting the "or an Agreement State."
20 We also did the same thing for parallel
21 structure on the (d)(2) to obtain a written
22 certification of whatever we are changing that to.
23 The preceptor, that's just attesting to their
24 training.
25 Or, if it was received in conjunction with

1 a residency program, then that written attestation can
2 be signed by the residency program director attesting
3 to the fact that they had successfully completed the
4 requirements of (c)(1), the 700 hours of training.
5 CHAIRMAN CERQUEIRA: Again, the question
6 of "certification" as opposed to some other word
7 will --
8 MS. McBURNEY: Right.
9 CHAIRMAN CERQUEIRA: -- be worked with.
10 MS. McBURNEY: I'm sure NRC staff can come
11 up with some word.
12 CHAIRMAN CERQUEIRA: A magic word.
13 Any other questions or discussions for
14 Ruth on .290?
15 MR. LIETO: This is Ralph. I have two
16 questions.
17 One, just clarification under (a) that has
18 the certification --
19 MS. McBURNEY: Uh-hum.
20 MR. LIETO: So does this mean that they
21 are certified in nuclear cardiology by the new
22 Certification Board of Nuclear Cardiology; they are
23 authorized for all imaging modalities, imaging -- is
24 that correct?
25 MS. McBURNEY: They can be, but --

1 MR. LIETO: So if they want to do --
2 MS. McBURNEY: -- we had a discussion of
3 that. At one time I had pulled out "nuclear
4 cardiology" as a separate specialty, but really as far
5 as the radiation safety aspects of it, it is the same.
6 CHAIRMAN CERQUEIRA: We had some
7 discussion, I think, during the meeting. We felt that
8 a lot of this would be done at the facility with
9 credentialing committees. We thought about putting
10 language in there that would try to sort of make
11 certain that cardiologists weren't doing brain scans,
12 but I think the general discussion was that was sort
13 of an issue of medical practice rather than a
14 radiation safety issue.
15 DR. WILLIAMSON: This is Jeff Williamson.
16 The ACMUI had a very long discussion that
17 ran about two years on this issue. The background was
18 that at some point it was decided to distinguish
19 between low-risk and high-risk modality.
20 In high-risk modalities the central
21 feature is that purely safety, especially radiation
22 safety, considerations could not be distinguished from
23 clinical experience or clinical competence, whereas
24 for low-risks they could.
25 So this was the result of a long

1 deliberation whereby it was decided that the nuclear
2 medicine imaging application should emphasize safety
3 and technical skills rather than clinical competence.
4 So it seemed unwise to reargue this whole large
5 philosophical issue since it was part of the initial
6 SRM from which the new Part 35 regulation was derived.
7 MS. McBURNEY: This is Ruth again.
8 Another aspect of that was that, as Dr.
9 Cerqueira mentioned or somebody, that the credible
10 practice for those individuals would probably limit
11 what they could do. A cardiologist would limit,
12 probably limit their practice to cardiology.
13 MR. LIETO: I just wanted to be sure that
14 that was the intent.
15 My other comment had to do, under the
16 Section (d) -- was that the alternative pathway with
17 the 700 hours? Under "work experience," (b), and this
18 occurs, I think, in other areas of
19 training/experience, it is a word -- it says,
20 "calibrating instruments used to determine activity."
21 I had a real problem with this calibration.
22 If I could make the recommendation of
23 using what Sally has under the Authorized Nuclear
24 Pharmacist, where they say, "use and perform checks
25 for proper operation," because they really don't

1 calibrate it. I think that is saying that the dose is
2 calibrating. They really don't calibrate dose
3 calibrations.
4 MS. McBURNEY: Right.
5 MR. LIETO: I imagine if you did, if you
6 got a special setting or something like that, but I
7 think the intent was really to have experience in
8 using and performing the checks for proper operation,
9 if I could just make that recommendation.
10 DR. EGGLI: This is Eggli.
11 I think that is correct, and you might use
12 a term such as "quality control procedures" because
13 the actual calibrations are done by the manufacturer.
14 CHAIRMAN CERQUEIRA: This is verbiage from
15 the old regs., and I think we can certainly make those
16 changes.
17 I just have one other comment, too, on
18 Part (2), I guess it is (d)(2), where it says, "signed
19 by the residency," again, a lot of the cardiology
20 programs, they are fellows. So it should be
21 "residency/fellowship program." It is a minor change,
22 but it would sort of make it a little bit clearer for
23 some of our constituencies.
24 MS. McBURNEY: Okay.
25 CHAIRMAN CERQUEIRA: All right, other

1 questions or issues in this part then?

2 MS. McBURNEY: Question. This is Ruth

3 again. Would that be true on the Uptake and Dilution

4 as well, that that would be a fellowship, could be a

5 fellowship?

6 CHAIRMAN CERQUEIRA: Well, I guess there

7 is probably a generic training program.

8 MS. McBURNEY: Okay.

9 CHAIRMAN CERQUEIRA: Yes, I don't think in

10 that situation it would necessarily be a fellowship.

11 MS. McBURNEY: I didn't think so.

12 CHAIRMAN CERQUEIRA: No.

13 DR. EGGLI: This is Eggli again.

14 For people like endocrinology fellows, it

15 could be a fellowship.

16 MS. McBURNEY: Yes.

17 CHAIRMAN CERQUEIRA: Yes.

18 DR. EGGLI: If you, again, would say,

19 "training program director" rather than "residency

20 program director," do you not cover both?

21 CHAIRMAN CERQUEIRA: You do. I guess we

22 could do it that way as well.

23 MS. McBURNEY: Okay.

24 CHAIRMAN CERQUEIRA: All right, so that

25 should take us through pretty much all of these

1 sections. I guess the one that we didn't cover that
2 Ruth said she was responsible for was 35.590, for Use
3 of Sealed Sources for Diagnosis.
4 MS. McBURNEY: Yes, this was a really
5 simple one. All I did was put back in the words that
6 had previously been accepted. In this one, in the
7 current rule there is no requirement for an
8 attestation of that training, for the eight hours of
9 classroom and laboratory training that are required.
10 So I just left it at that without having
11 "attestation." I didn't bring that up for discussion.
12 CHAIRMAN CERQUEIRA: John, did you have a
13 comment?
14 MR. HICKEY: Yes. this is John Hickey.
15 I agree this is a simple section, but I
16 would point out the last line about training on the
17 use of the device, it raises the issue that really we
18 focused on in .690 about the modality. So it seems to
19 me that that should be separated out as a separate
20 paragraph, so that the board certification process
21 does not have to include training in the use of the
22 devices, unless that is the case.
23 MS. McBURNEY: It doesn't
24 DR. WILLIAMSON: Yes. This is Jeff
25 Williamson, and I support that change, too: Make a

1 Section (d) which says, "in addition to satisfying
2 Parts (a), (b), or (c) above" --
3 MS. McBURNEY: What would the criteria for
4 another specialty board then be?
5 DR. WILLIAMSON: Well, you see, the
6 concern is that the American Board of Radiology, say
7 therapeutic radiology, would not meet the criterion
8 (b), which says, all diplomates have to have training
9 in the use of this particular device.
10 MS. McBURNEY: Oh, I see.
11 DR. WILLIAMSON: So the suggestion is to
12 create a Section (d) which is parallel to the device-
13 specific or modality-specific training that we have
14 had with some of the others.
15 MS. McBURNEY: Okay. So if I --
16 DR. WILLIAMSON: Just take No. (c)(5)
17 away --
18 MS. McBURNEY: Right.
19 DR. WILLIAMSON: -- and make a Section (d)
20 which says, in addition to complying with the
21 requirements of (a), (b), and (c), an authorized user
22 for such-and-such shall have training in the use of
23 the specific device for the uses requested.
24 MS. McBURNEY: Okay.
25 CHAIRMAN CERQUEIRA: Ruth, are gadolinium

1 sources covered under this?
2 MS. McBURNEY: Are what?
3 CHAIRMAN CERQUEIRA: Gadolinium sources
4 for attenuation correction, I mean, is that covered
5 under this or --
6 MS. McBURNEY: No. That is covered with
7 the diagnostics.
8 CHAIRMAN CERQUEIRA: It is? Okay.
9 MS. McBURNEY: But the gadolinium sources
10 here are not used for diagnostics. These are like
11 bone densities.
12 CHAIRMAN CERQUEIRA: Okay. All right
13 MS. McBURNEY: Yes.
14 DR. WILLIAMSON: So these would probably
15 be americium.
16 CHAIRMAN CERQUEIRA: Right, okay.
17 Do people agree in Jeff's suggested
18 changes to sort of keep it in parallel with some of
19 the other areas?
20 DR. VETTER: Vetter agrees.
21 MS. McBURNEY: That makes sense.
22 CHAIRMAN CERQUEIRA: Yes, okay. All
23 right, well, that takes us through this portion of the
24 document. We were supposed to take a break at 2:45,
25 but is the Committee in favor of continuing, pushing

1 on to get done?

2 DR. EGGLI: I favor pushing on.

3 CHAIRMAN CERQUEIRA: Okay. Because the

4 remaining items aren't really -- we just have to

5 review a couple of other areas.

6 So, John, do you have any other comments

7 that you would like to make at this point? Because we

8 seem to have gotten fairly good consensus on all of

9 these. At this point should the Committee take a vote

10 formally now or would it be better for the Committee

11 to have some time to think about this and then make

12 comments?

13 MR. HICKEY: This is John Hickey.

14 I mean, ideally, the earlier vote, the

15 better, but it seems to me that, even if we take a

16 vote now, that should be subject to review of the

17 edited version that we would send out to the Committee

18 to see if they wanted to add any comments or point out

19 any errors that they notice.

20 CHAIRMAN CERQUEIRA: What are the wishes

21 of the Committee on how to proceed on this? Approve

22 it, pending review of the revisions?

23 DR. VETTER: This is Richard Vetter.

24 I think the suggestions for editing,

25 improvement, et cetera, have been very

1 straightforward. I would vote for voting for approval
2 now, contingent on seeing the revision, so that we
3 don't have to take a formal vote later.
4 DR. MALMUD: If that's the motion, I will
5 second it.
6 CHAIRMAN CERQUEIRA: Okay, we have a
7 motion and a second. Any discussion? Anyone have
8 disagreements on doing that? Dr. Malmud?
9 DR. MALMUD: Malmud seconding it.
10 DR. BRINKER: This is Brinker.
11 Just as a sort of point of order, does
12 that mean that there will be no second vote on the
13 final product?
14 CHAIRMAN CERQUEIRA: Well, I guess people
15 could give us written comments. But I guess if we
16 approve it, then technically it has been approved.
17 DR. EGGLI: I think it means that if you
18 see the draft or the revised draft and you don't like
19 it, I think you can retract your vote.
20 DR. BRINKER: Well, I don't think that's
21 good.
22 MR. LIETO: No. This is Ralph Lieto.
23 I tend to echo Dr. Brinker's concerns that
24 voting on something before we have seen the final
25 written version I think I have some great concern

1 with. So I would oppose taking a formal vote on
2 approving it without having a written document in
3 front of me.
4 DR. NAG: This is Subir Nag.
5 I think what we can do, we can vote
6 online. I mean we can say we approve online. That
7 way we won't have to have a separate meeting.
8 CHAIRMAN CERQUEIRA: Right. I think,
9 John, would that be acceptable for the --
10 MR. HICKEY: Yes, yes, and I would suggest
11 that people could vote "approve with comments." We
12 can append the comments to the report. If a Committee
13 member feels they have a comment but they don't want
14 to vote "disapprove," they could still vote approved
15 and add their comment.
16 CHAIRMAN CERQUEIRA: So we do have a
17 motion. Does the Committee -- it sounds like
18 basically get the final text revised, sending it out
19 to the Committee members, and then getting their vote,
20 either a fax or an email vote on the final motion,
21 giving people the opportunity to make specific
22 comments, and if there's significant disagreement, I
23 guess we could convene another conference call. Does
24 that sound acceptable to the Committee?
25 (Multiple members respond "yes" at the

1 same time.)

2 CHAIRMAN CERQUEIRA: Okay, let's go ahead

3 and do that then.

4 All right, so the other two items on the

5 agenda, then, are basically the Agreement State

6 Implementation of the 10 CFR Part 35 Training and

7 Experience Requirements. I asked John to put this on

8 the Committee agenda because I think we've got a new

9 rule which has been published and goes into effect on

10 October 24th, and then we have like a two-year period

11 during which you can either apply by the old or the

12 new Part 35, and the Agreement States have three years

13 upon which to either become compliant with the NRC or

14 make some statement as to whether they would like to

15 have alternative rules.

16 So it is going to be quite -- it is going

17 to be very chaotic out there. When the Commissioners

18 approved this, the agreement Level, the Agreement

19 State was Level C, John, is that --

20 MR. HICKEY: No, B. I'm going to ask Mr.

21 Lloyd Bolling to join us at the table at a microphone,

22 from our Office of State and Tribal Programs, and we

23 can go through this.

24 CHAIRMAN CERQUEIRA: Okay.

25 MR. HICKEY: But the compatibility level

1 is what is called B, which is essentially identical.
2 CHAIRMAN CERQUEIRA: Right.
3 MR. HICKEY: So the only issue is timing.
4 It is not whether they are required to implement
5 compatible rules.
6 Lloyd Bolling has now joined us.
7 MR. BOLLING: That is correct, John. The
8 Agreement States have been given three years from the
9 October '02 date. So that means that on October of
10 2005 the Agreement States will have to have a
11 compatible rule, all parts of the rule, including the
12 T&E requirements. The two-year transition period
13 within which the old and the new may be accepted is
14 within the three-year compatibility period.
15 Now during the promulgation of Part 35,
16 which will go into effect this year, the Agreement
17 States, some organizations I believe petitioned the
18 Commission to have the implementation be sooner than
19 three years, but the Commission has clearly indicated
20 that they want the Agreement States to have the full
21 three years. So that's where we are at this point.
22 CHAIRMAN CERQUEIRA: That would be ideal.
23 I just sort of recall that in the early nineties the
24 Glenn Commission sort of looked at the NSC and the
25 Agreement States, and one of their conclusions was

1 that there is no enforcement mechanism at the federal
2 level if the states are not in compliance. So I am
3 just not sure that if the states decide not to
4 necessarily enforce things the way the federal regs.
5 have been written, does the NRC have the ability to
6 enforce it?
7 MR. BOLLING: I am not sure enforcement is
8 the right word to use, but when it comes to
9 compatibility, those regulations or program elements,
10 and regulations are among the program elements, that
11 are deemed to be high matters of compatibility are
12 reviewed by us on a regular basis when the rules are
13 being promulgated as well as just before one of our
14 routine, periodic audits of the state programs. So
15 that when we go out and audit a program, if we find
16 that a certain portion of a rule has not been adopted
17 or the whole rule itself has not been adopted, the
18 state will not get an adequate review for that period.
19 As you know, the agreement is between the
20 governor and the Chairman of the Commission. So if,
21 in fact, some health and safety issue has not been
22 addressed, we can go directly to the governor and
23 discuss with the governor what we consider to be a
24 lapse in the regulation. Usually, that is enough to
25 get the regulation passed.

1 CHAIRMAN CERQUEIRA: Okay, again, maybe I
2 am just being too concerned about something that will
3 work out, but, again, it can be very chaotic out there
4 unless we get very good agreements. So I just kind of
5 wanted to bring that up as an issue.
6 Ruth, do you think the Agreement States,
7 which are clearly the majority of states now, will
8 pretty much go along with the revised Part 35 and then
9 the revision of the Training and Experience
10 Requirements?
11 MS. McBURNEY: Yes, I'm pretty sure that
12 they will. For some states the process takes a little
13 longer than it does with others. Some states have to
14 take their rules to a legislative committee; others
15 just to their rulemaking body, which for a health
16 department could be a board of health or a commission,
17 if it is an environmental agency. So the time that it
18 takes to get those rules adopted is going to vary.
19 I know that the Nuclear Regulatory
20 Commission is training this summer for implementing
21 Part 35, and a lot of the Agreement State personnel
22 are participating in that regional training. It is
23 going to be put on at, I guess, the regional offices,
24 is that right, Lloyd?
25 MR. BOLLING: That is correct, yes.

1 MS. McBURNEY: And we have had it brought
2 up at national meetings. So everybody is really aware
3 of the rules and the changes. So it is just a matter
4 of getting it done. It is going to vary from state to
5 state for a while, but I think within that two-to-
6 three-year timeframe you will see them getting them
7 adopted.
8 CHAIRMAN CERQUEIRA: Well, good, that is
9 reassuring.
10 Any other comments from the Committee?
11 (No response.)
12 Okay, the last thing on the agenda then is
13 the Status of the New ACMUI Appointments and Future
14 Vacancies. John, do you have an update on that?
15 MR. HICKEY: Yes, I am going to ask Angela
16 Williamson to join us at a microphone just for a
17 moment. I am going to ask Angela to correct me if I'm
18 wrong.
19 In 2003 the only appointments are people
20 that are eligible for reappointment. There are five
21 of those: Dr. Diamond, Dr. Nag, Ms. Schwartz, Dr.
22 Williamson, and Dr. Vetter. I am not sure, Angela,
23 whether all of them have indicated an interest in
24 reappointment or have we not heard back from some of
25 the people yet?

1 MS. WILLIAMSON: This is Angela
2 Williamson.
3 The people that I have a definite
4 commitment to another term from are Dr. Diamond, Dr.
5 Williamson, and Dr. Vetter.
6 MR. HICKEY: I should point out people are
7 not obligated at this point to indicate whether they
8 are willing to be reappointed, but they will need to
9 indicate that in the future, so that we can arrange
10 the followup by 2003.
11 CHAIRMAN CERQUEIRA: I think in 2004 I
12 rotate off, and Ruth McBurney will be rotating off.
13 So I think one of the discussion that we
14 had at the full Committee meeting was to try to do the
15 appointments in a more timely fashion, so we avoid the
16 vacancies. I think we should formally contact all the
17 people that are up for reappointment in 2003 and see
18 if they are interested in being reappointed. If they
19 are not, then we should basically request new
20 appointees for those positions. I guess sometime next
21 year we should sort of do the same for the two people
22 that will be rotating off the following year.
23 MR. HICKEY: Yes, we agree, and our
24 Directors have indicated their agreement that we need
25 to make sure these things are done with adequate lead

1 time, so that there is no standing vacancies.

2 CHAIRMAN CERQUEIRA: Good. Well, I think

3 that pretty much concludes the formal agenda of the

4 Committee. I did say that we would have the

5 opportunity for the public, and there is actually only

6 four people sitting out there in the public here at

7 the NRC headquarters, to make comments.

8 So, Mr. Uffelman, Bill Uffelman, legal

9 counsel for SNM, wishes to --

10 MR. UFFELMAN: Never letting a moment to

11 comment on something pass me by, I am Bill Uffelman.

12 I am the General Counsel and Director of Public

13 Affairs for the Society of Nuclear Medicine. Just a

14 couple of nitpicking comments, I suppose, but it is

15 what I get paid for.

16 Section 35.55, under the Nuclear

17 Pharmacist, the language at the new or what is now

18 (c)(3) I think is inappropriate. The reference to

19 (b)(2) of this section doesn't make any sense anymore.

20 That went back to 35.55 as printed in The Federal

21 Register.

22 I think what we are trying to say, or what

23 you really want to say because of the rewrite that

24 became (c)(1) and (2) is that (3) needs to say,

25 "listed in (c)(1) and (2) of this section," But

1 having only spent a few minutes looking at it, I think
2 that is correct.
3 MS. SCHWARTZ: I think that I understand
4 the comment, and I think it should be (b)(3). I think
5 the issue is the certification or the attestation,
6 which is now in (b) -- or, excuse me, (c)(2). The
7 Supervised Practical Training needs to be attested to
8 by the board-certified nuclear pharmacist. But they
9 are not certifying the didactic training. So it
10 should be just --
11 MR. UFFELMAN: It should be "Charlie" 2,
12 not "Bravo" 2.
13 MS. SCHWARTZ: Excuse me?
14 MR. UFFELMAN: It should be, at least what
15 was handed out here locally, it should be then (c)(2),
16 not (b)(2) because you changed your -- you're in
17 "Charlie," not "Bravo." Okay. I will buy that. I
18 have no problem with that.
19 MS. SCHWARTZ: That is correct.
20 MR. UFFELMAN: Okay. Then, I'm sorry, I'm
21 standing up holding all this stuff, and I've got to
22 find the right page before I dump everything.
23 The training in 35.390, and numerically I
24 think it is 4(g)(1), (2), (3). It was the area where
25 you were talking about the sodium iodide, I-131. I

1 think that should be "of" rather than "or" in (g)(1)
2 and (g)(2). Otherwise, grammatically, it makes no
3 sense.
4 MS. SCHWARTZ: Yes.
5 MR. UFFELMAN: In the beginning, when you
6 were talking about 35.390, I believe it was Dr. Malmud
7 who asked a question about the -- or the question came
8 up as to the three-year residency programs, and the
9 comment was made, "Well, those are grandfathered or
10 the existing ones are grandfathered."
11 But, in fact, this is the prospective
12 section, so that in fact the ABR program, (b)
13 residency in radiology, or something else with a two-
14 year fellowship, would that, in fact, be covered in
15 (a)(1)? The comment was made, "Well, this was just
16 grandfathered."
17 I am looking forward prospectively. Are
18 you, in fact, covering all the programs you intend to
19 cover? I know you want to cover them, but did you, in
20 fact, capture that in that language?
21 DR. WILLIAMSON: This is Jeff Williamson.
22 I believe that Dr. Uffelman is correct
23 that we should change this to be a minimum three-year
24 residency, including -- "that includes 700 hours of
25 nuclear medicine training," something like that.

1 DR. MALMUD: But may I suggest that it be
2 a "minimum of three years of residency" rather than a
3 "three-year residency"?
4 DR. WILLIAMSON: Yes, and then indicate a
5 duration of nuclear medicine training that fits with
6 what was negotiated in previous years, it seems to me
7 would be reasonable.
8 MR. HICKEY: This is John Hickey.
9 Could I clarify, are we looking at
10 .390(a)(1)?
11 MR. UFFELMAN: Correct.
12 DR. MALMUD: Yes.
13 MR. UFFELMAN: I think what they want to
14 capture -- ABR's staff representative is here, too.
15 We try and huddle on some of this stuff. They want to
16 capture that a person who has been in a radiology
17 training program which encompasses nuclear medicine is
18 qualified, as is a nuclear medicine physician, or
19 somebody who has done a nuclear medicine residency.
20 Am I correct that's what you are trying to capture?
21 DR. WILLIAMSON: That was my
22 understanding. This is Jeff Williamson.
23 DR. VETTER: This is Richard Vetter. That
24 was my understanding as well.
25 MR. UFFELMAN: So, yes, you do need to fix

1 the language, whatever the fix is that you want to do.
2 Other than that, I think we've got
3 everything. We were huddling back here when you were
4 talking about -- and it was a carryforward of the
5 language, but when you look at .590, it says, look at
6 35.590 in (a) "is certified in radiology" under
7 (a)(1), and then in (a)(2) it says "nuclear medicine
8 by the American Board of Nuclear Medicine." There is
9 no specific reference to nuclear medicine. You know,
10 it is a presumption that nuclear medicine is
11 encompassed in the radiology certification, is that
12 correct?
13 In an ABR radiology certification, that
14 encompasses nuclear medicine because there is a point
15 back here in one of the other sections where you, in
16 fact, break out and say, "in nuclear medicine by ABR."
17 MR. LIETO: You mean a special competency
18 -- this is Ralph Lieto -- you mean a special
19 competency in nuclear medicine?
20 MR. UFFELMAN: Right. Yes, I've got to
21 find the language. I'd better have all the pages
22 flagged here, like I should have.
23 DR. VETTER: This is Richard Vetter.
24 My understanding of radiology, it would be
25 old radiology. It is not current diagnostic

1 radiology. But the old radiology included therapeutic
2 radiology.
3 MS. FAIROBENT: This is Lynne Fairobent
4 with the American College of Radiology.
5 Ralph, the question, and I guess Dr.
6 Eggli, the question is, does ABR have a separate
7 certification in nuclear medicine from diagnostic
8 radiology? What's been brought forward is the current
9 language that's in the existing Subpart (j), but my
10 question is, does ABR actually have a separate nuclear
11 medicine certification in addition to the diagnostic
12 radiology certification?
13 DR. VETTER: No, the diagnostic radiology
14 was special competency, I think is what they have in
15 ABR.
16 DR. EGGLI: This is Eggli.
17 It is actually these days called a
18 Certificate of Added Qualification.
19 MS. FAIROBENT: Okay, and then I guess my
20 question is, do we have to do anything to change to
21 reflect the words that are being proposed in these
22 sections? Because on unnumbered page, but it would be
23 -- Section 35.390(c)(1) states that, "Boards currently
24 recognized by the Commission to meet all the
25 requirements of paragraph (a) of this section include

1 the American Board of Nuclear Medicine and the Nuclear
2 Medicine sections of the American Board of Radiology."
3 So that wording in that particular section
4 on .390 is different than the wording in .190 and .290
5 and .590.
6 MR. HICKEY: This is John Hickey.
7 What is the significance of that
8 difference? What's the concern?
9 MS. FAIROBENT: My concern is that we
10 don't drop out radiologists who are practicing nuclear
11 medicine.
12 MR. HICKEY: Okay.
13 MS. FAIROBENT: Or it is being nuclear
14 medicine physicians certified by the American Board of
15 Nuclear Medicine.
16 MR. HICKEY: The understanding was that
17 all of these existing board certifications were going
18 to be re-reviewed and determined whether they met
19 certain criteria before they were listed. So at that
20 time a determination would be made whether they are
21 titled correctly. Is that your concern?
22 MS. FAIROBENT: Well, that and, also,
23 consistent language from one section to the other as
24 you are referring to the board --
25 MR. HICKEY: Well, it was discussed

1 earlier that the language needs to be consistent from
2 section to section.
3 DR. WILLIAMSON: Well, Jeff Williamson,
4 and I think this whole section needs to be rewritten
5 fairly carefully. You know, it seems it would help,
6 first of all, if we put the listing of the boards
7 maybe at the beginning to get that straightened out
8 and then came up with some wordsmithing that gets
9 across the point, which was I think the emphasis, the
10 Subcommittee's consensus was that there should be a
11 three-year residency in something, some field. It
12 just shouldn't be 700 hours of training alone because
13 this is a high-risk modality.
14 The idea, I think, was the three-year
15 residency in radiology, with the minimum 700 hours of
16 practice in nuclear medicine or certification in
17 radiation oncology, and I guess we would have to maybe
18 break out what the other options would be to make sure
19 we don't leave anyone out. Because the intent was to
20 cover all of the other groups that were allowed to
21 practice this indication, not excluding.
22 DR. MALMUD: My suggestion -- this is
23 Malmud again -- my suggestion was that we use the term
24 "three years of residency" so that we would not
25 exclude either radiologists who took one year of

1 training in nuclear beyond their radiology program or
2 nuclear physicians who only had two years of nuclear
3 medicine residency above their basic training in
4 either radiology or medicine or some other field.
5 DR. WILLIAMSON: Yes.
6 DR. MALMUD: And that is why I thought the
7 term "three years of residency," rather than a "three-
8 year resident" would rather be prescriptive.
9 DR. WILLIAMSON: How would you capture the
10 -- or how would you exclude somebody who has a three-
11 year residency in dermatology or something and zero
12 experience or zero significant experience with
13 ionizing radiation medicine?
14 DR. MALMUD: Don't the requirements for
15 the components of the training program remain, even
16 though they have had as requirements of the three
17 years of training? In other words, are we not
18 requiring that there be some experience within those
19 three years?
20 DR. NAG: The problem, I think, of the
21 acceptability at three years of residency is that
22 almost every physician has three years of residency.
23 They may be in something closely associated to either
24 radiology and nuclear medicine or radiation oncology.
25 So unless you have those words either "radiotherapy or

1 nuclear medicine," standards become essentially
2 irrelevant.
3 DR. WILLIAMSON: All right. Dr. Nag would
4 suggest maybe we put three years of residency in
5 radiation oncology or three years of residency in
6 radiology or a related field that includes at least
7 blah, blah, blah hours of nuclear medicine, imaging
8 experience.
9 DR. MALMUD: That sounds like an
10 improvement.
11 CHAIRMAN CERQUEIRA: Well, I think Jeffrey
12 should make these changes and then sort of get them
13 out for comment, so we get full clarification on this,
14 and I guess sort of get all the involved parties to
15 make comment.
16 DR. WILLIAMSON: Okay, hearing that I am
17 now assigned the task of rewriting of 35.390 --
18 (Laughter.)
19 MR. HICKEY: Well, this is John Hickey.
20 Unfortunately, Dr. Diamond had to leave early, but I
21 am sure he would be willing to assist when he's
22 available.
23 On that point, Dr. Cerqueira, Dr. Vetter,
24 I would ask, do you feel you, with the Subcommittee,
25 are in a position to develop the revised draft?

1 DR. VETTER: This is Richard Vetter. Yes,
2 I do.
3 MR. HICKEY: Okay.
4 CHAIRMAN CERQUEIRA: And we should come up
5 with a timeline on this as well, because this is the
6 8th, and we really -- Dick, realistically, how long do
7 you think it is going to take your Subcommittee to
8 turn this around?
9 DR. VETTER: This is Richard Vetter.
10 Well, up until a few minutes ago, I thought we could
11 do it in a couple of days.
12 (Laughter.)
13 But now with the potential rewrite of .390
14 here --
15 CHAIRMAN CERQUEIRA: Well, what's the
16 Committee's feeling? I mean, I think the issues that
17 have been brought up are -- we don't have David on the
18 line, unfortunately. Jeffrey, what do you think?
19 DR. WILLIAMSON: I can try to turn it
20 around in a couple of days because later this week the
21 AAPM Annual Meeting starts that I'm going to be
22 unavailable for the next week.
23 CHAIRMAN CERQUEIRA: I think if we made it
24 a week from today, the 15th, that would be ideal.
25 DR. VETTER: Sally, are you able to get

1 your -- this is Richard Vetter -- are you able to get
2 your section to me a week from today?
3 MS. SCHWARTZ: Yes, I will do that.
4 Actually, I am on vacation this week, but I have my
5 computer with me, so I will contact people I need and
6 I am sure I can have it to you in a week.
7 DR. VETTER: Okay.
8 CHAIRMAN CERQUEIRA: So we will aim for
9 the 15th.
10 Ruth, do you think you could -- you don't
11 have too many revisions on yours.
12 MS. McBURNEY: This will be pretty simple.
13 I can do that in a couple of days then.
14 CHAIRMAN CERQUEIRA: So if we did it by
15 the 15th, and then the staff has some verbiage to come
16 up with for some of these things, and --
17 MS. McBURNEY: So we send them all to Rich
18 again?
19 DR. VETTER: Yes.
20 MS. McBURNEY: Okay.
21 CHAIRMAN CERQUEIRA: Yes, and then he
22 would send it around to the staff. When does the
23 staff, if they get everything by the -- Dick, I think
24 your job should basically just be to coordinate and
25 then pass it on.

1 DR. VETTER: I agree, yes. This is
2 Richard Vetter. If everyone could send me their
3 revisions, I will make sure it all gets incorporated
4 into a single draft, and I will forward that to NRC
5 staff for distribution to the Committee.
6 DR. NAG: By the way, if when you are
7 doing that you can do it on the edit mode, where you
8 have exact changes on, it is a lot easier to see what
9 was changed, rather than having to go through the
10 entire document.
11 DR. VETTER: Okay. This is Richard
12 Vetter. Would the Committee like to see it in edit
13 mode?
14 MR. HICKEY: That means there would be
15 redlines and strikeouts marked on it, correct?
16 DR. VETTER: That's correct, yes.
17 DR. NAG: And if you don't like it, you
18 can always turn it off. As you go through the top,
19 you can turn it off.
20 DR. VETTER: Right.
21 CHAIRMAN CERQUEIRA: But does the staff,
22 if you get it on the 17th from Dr. Vetter, do you
23 think you could get it out to the people by the 19th
24 of July?
25 MR. HICKEY: Yes, we would intend to get

1 it back out the same week. We would like to know from
2 the Committee how long they would like to review it.
3 Again, I suggested that if you want to approve with
4 comments, that could be a type of vote, as opposed to
5 just a straightforward approval or disapproval.
6 Hopefully, there wouldn't be any disapprovals.
7 CHAIRMAN CERQUEIRA: So if we get
8 everybody to send it over two weeks, or three weekends
9 and two weeks in between, if we go for August the 5th,
10 would that give everyone enough time?
11 MS. SCHWARTZ: Yes, it would.
12 DR. VETTER: Yes.
13 CHAIRMAN CERQUEIRA: Okay, then we could
14 basically, once we have gotten that, we could take the
15 comments and see the level of disagreement, and I
16 guess we could make a decision at that point whether
17 we should send it out for -- if there are substantive
18 disagreements, then we could basically convene another
19 conference call.
20 Does that sound like a reasonable timeline
21 and game plan on this?
22 DR. VETTER: Yes, that sounds reasonable.
23 MS. SCHWARTZ: Yes, it does.
24 CHAIRMAN CERQUEIRA: Okay. I appreciate
25 Sally's giving up part of her vacation to do this.

1 (Laughter.)
2 MS. SCHWARTZ: Thank you.
3 CHAIRMAN CERQUEIRA: Okay, I have no other
4 -- any new business or any other items that people
5 would like to discuss?
6 MS. SCHWARTZ: And we will be editing the
7 June 27th, 2002 version in edit mode? Is that
8 correct?
9 DR. VETTER: That is correct.
10 CHAIRMAN CERQUEIRA: Right.
11 DR. WILLIAMSON: Jeff Williamson here.
12 CHAIRMAN CERQUEIRA: I knew Jeff would
13 have something.
14 DR. WILLIAMSON: Briefly, for John Hickey,
15 what is the overall process that this document is
16 going to undergo or this effort is going to undergo
17 after the preparation and approval of this document by
18 the ACMUI?
19 MR. HICKEY: This is John Hickey.
20 The Commission has asked the staff to
21 provide options prior to the effective date of the
22 rule, prior to October 24th, for their review. That
23 would include the recommendations of the Committee as
24 well as other options identified by the staff, which
25 could include no change. It could include adopt the

1 ACMUI recommendations, and it could include other
2 options.
3 So the recommendations of the Committee
4 will be incorporated into that transmittal to the
5 Commission prior to October 24th, but then the
6 Commission will have to review that. It is too early
7 now to try to predict how long it would take for the
8 Commission to decide what they are going to do about
9 this issue.
10 DR. WILLIAMSON: Is there any opportunity
11 for the ACMUI to have some input or express its
12 opinions about the other option?
13 MR. HICKEY: We haven't determined that
14 yet, but we can talk more with the Committee and look
15 into that.
16 DR. WILLIAMSON: I mean, it just would
17 seem to me to be, given how difficult this issue has
18 been, if the Committee could have some kind of a
19 briefing or some opportunity to express its view about
20 the overall white paper that you are going to present
21 to the Commission, including, you know, the other
22 option --
23 MR. HICKEY: We will look into that. I
24 can't speak for the Commission as to what they want to
25 do, but that is certainly a reasonable request.

1 DR. WILLIAMSON: This is before it gets to
2 the Commission.
3 MR. HICKEY: Well, but the Commission has
4 to agree on what the arrangements are.
5 DR. WILLIAMSON: Well, yes, I understand
6 they have to make a decision and they will or will not
7 consult us, depending on what they want to do, but it
8 sounds like our document is going to be a subset of a
9 larger document that your staff is going to prepare.
10 MR. HICKEY: That is correct.
11 DR. WILLIAMSON: So what I'm asking is, do
12 we have any opportunity to express our opinion or
13 views on the other components of the document that are
14 contributed by your staff?
15 MR. HICKEY: I understand that. I say we
16 have not specifically arranged for that, but we will
17 look into that. But since it is a communication with
18 the Commission, we also have to coordinate that with
19 the Commission, both with respect to the timing and
20 the substance, but we certainly will look into that.
21 CHAIRMAN CERQUEIRA: And, John, when you
22 tentatively set up a meeting for the ACMUI Committee
23 with the Commissioners on October 28th and 29th, which
24 are a Monday and Tuesday, would we have a time then to
25 discuss this with them?

1 MR. HICKEY: Well, I don't think that that
2 is a meeting with the Commission. I don't recall --
3 I think that is the ACMUI meeting, but did we agree
4 that that was going to be a meeting with the
5 Commission? Because you met with the Commission
6 earlier this year. But, again, we could ask if the
7 Commission can meet with the Committee, not just make
8 the written communications.
9 CHAIRMAN CERQUEIRA: Well, I think what
10 Jeff and some of the other Committee members are
11 suggesting is that it would be appropriate. We have
12 spent a lot of time on this, and we certainly would
13 like to get some feedback as well as have some
14 interaction with these --
15 MR. HICKEY: But Dr. Williamson is also
16 asking about having prior review and comment, even
17 before this goes to the Commission, but both of those
18 could be arranged, the prior interaction and also a
19 face-to-face meeting with the Commission.
20 DR. WILLIAMSON: Well, in view of the
21 importance of this to the regulated community, and the
22 conduct of radiation medicine, I think it wouldn't be
23 a bad idea to have -- the more views, I should think
24 the better your report would be, that it would be
25 ultimately to the Commission's advantage to have

1 additional feedback on the other alternatives that the
2 staff comes up with.
3 CHAIRMAN CERQUEIRA: So I guess it is the
4 feeling of the Committee and the view from the other
5 people is to basically try to get more feedback to the
6 Commissioners as well as try to meet with them on this
7 specific issue? Is that what people are saying?
8 DR. WILLIAMSON: I guess I would put it as
9 a form of a motion, if you would like. So that is a
10 motion, that we should have an opportunity to discuss
11 the final report with the Commission and have an
12 opportunity to give some feedback on the report
13 prepared by the staff prior to submission to the
14 Commission.
15 DR. MALMUD: I'll second that motion.
16 CHAIRMAN CERQUEIRA: Okay, any further
17 discussion?
18 (No response.)
19 All those in favor of the proposal?
20 Any opposed?
21 I think it is pretty unanimous, John.
22 It's easy for John to say; he's not going to be here.
23 Okay, well, I think that ends our
24 business.
25 MS. SCHWARTZ: Could I ask one thing?

1 CHAIRMAN CERQUEIRA: Yes.
2 MS. SCHWARTZ: Could you paginate the
3 document when you send it back?
4 DR. WILLIAMSON: I will do that.
5 MS. SCHWARTZ: Thank you.
6 DR. WILLIAMSON: Sure.
7 CHAIRMAN CERQUEIRA: I would like to thank
8 the committee for excellent work, and our minimalist
9 audience out here. Thank you.
10 (Whereupon, the foregoing matter went off
11 the record at 3:36 p.m.)
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